CLINITEK® 500

Urine Chemistry Analyzer

Operating Manual

SECOND EDITION

Manufactured in the UK for Bayer

Bayer HealthCare LLC
Subsidiary of Bayer Corporation
Tarrytown, NY 10591-5097 USA

EC REP

Bayer Diagnostics Europe Limited
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INTRODUCTION

General Description and Intended Use

The CLINITEK® 500 Urine Chemistry Analyzer (Figure 1-1) is a semiautomated, benchtop instrument designed to "read" traditional Bayer Reagent Strips for Urinalysis (e.g., MULTISTIX® 10 SG) and Bayer MULTISTIX PRO® family of Reagent Strips. The instrument system includes a program card that contains the programming necessary for the CLINITEK 500 instrument to read these Reagent Strips. Strips can be laid on the instrument at any time (if specimen IDs are not used); a sensor detects the strip's presence, which activates the strip movement and reading cycle. Communication between the instrument and the user is through the use of a touch screen and interactive software.

Figure 1-1

Depending on the product being used, Bayer Reagent Strips contain reagent areas for testing glucose, bilirubin, ketone (acetoacetic acid), specific gravity, occult blood, pH, protein, urobilinogen, nitrite, and leukocytes. In addition to these tests, MULTISTIX PRO Reagent Strips also contain protein–low and creatinine reagent areas. A single protein result is reported from the two protein tests; this reading is compared to the creatinine result to provide a protein-to-creatinine ratio. The instrument can also determine and report the color of the urine, and the clarity can be entered for each specimen.

The instrument is a reflectance spectrophotometer that analyzes the color and intensity of the light reflected from the reagent area and reports the results in clinically meaningful units (see Tables 1-1 through 1-6). No calculations are required by the user. Calibration is performed automatically each time a Reagent Strip is analyzed.

Components and Mechanical Operation

Figures 1-2 and 1-3 show the major components of the CLINITEK® 500 instrument. The program card is inserted into the card receptacle (1). The strips are transported across the read area (2), where incubation and reading of the tests occur. All test results are printed by the internal thermal printer (3) (unless this option has been selected as "OFF" by the operator). All communications between the operator and the instrument are made through the interactive touch display (4). Response keys and dialogue are displayed on the screen; responses are made by touching the appropriate key symbol on the screen.

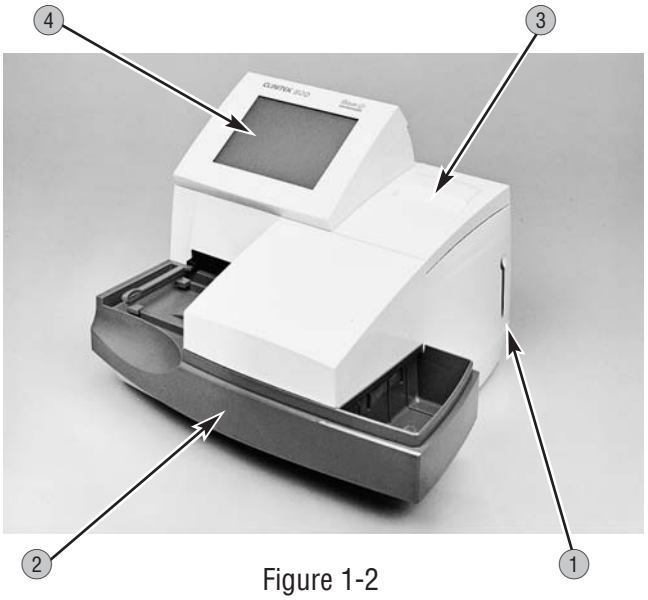


Figure 1-2

The fixed platform (5) consists of three sections: the strip loading station (5a), the incubation/read station (5b), and the waste bin (5c). A Reagent Strip is placed onto the instrument at the strip loading station. Detection of a strip by the strip sensor (6) causes the instrument to begin cycling. The strip is moved toward the incubation/read station by the push bar (7). The strip is then moved through the incubation/read station by a series of pins; the pins move the strip at a rate of about ½ inch every 7 seconds.

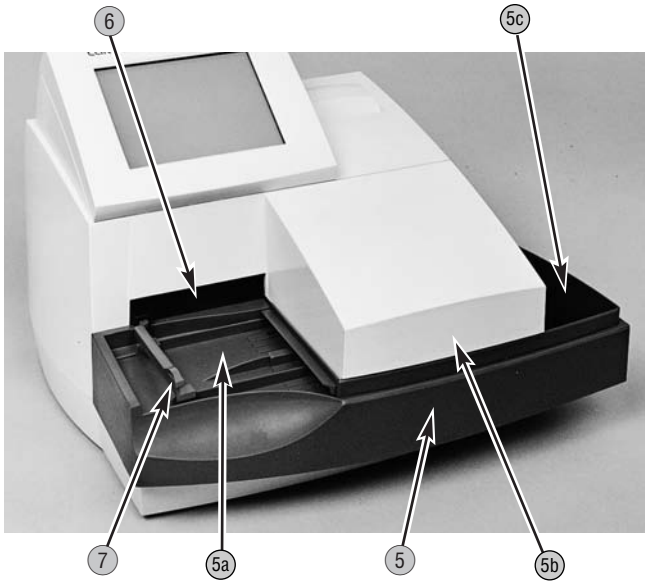


Figure 1-3

Two readheads, located inside the read area, scan the length of each Reagent Strip at a specific time in the incubation cycle. The first readhead reads the reagent areas requiring shorter incubation times; the second reads those requiring longer incubation times. The pins continue to move the strip along the platform until it drops into the waste bin.

Figure 1-4 shows the rear view of the CLINITEK 500 instrument. The line cord is connected into the line cord receptacle (8). The instrument is turned *on* by pressing the power switch (9) to the ON ("—") position. The interface connectors (10) are the points at which a computer, printer, and/or handheld bar code reader may be interfaced with the instrument. An extra port is available for future use. The instrument is cooled by a fan (11).

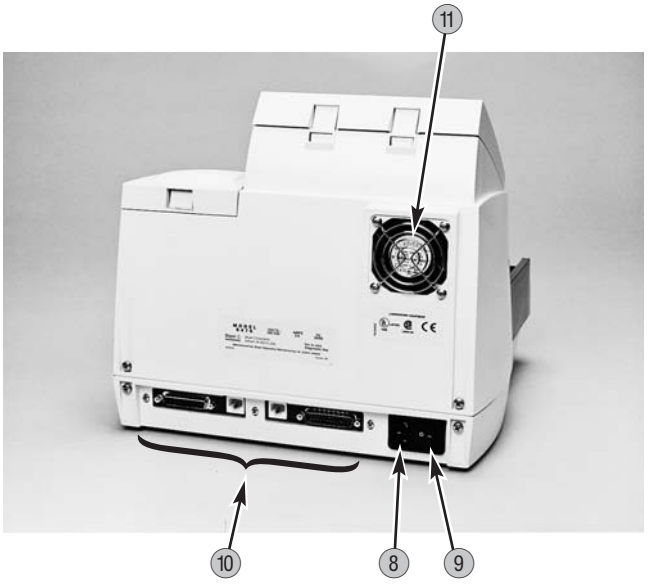


Figure 1-4

All programming for the instrument is contained in a replaceable program card (12), shown in Figure 1-5. The card is programmed with such information as error messages, operating sequence, and the wavelengths and algorithms used to convert reflectance into clinically meaningful results. It also contains the customized Setup information selected by the user. The card is easily replaceable for future software updates.

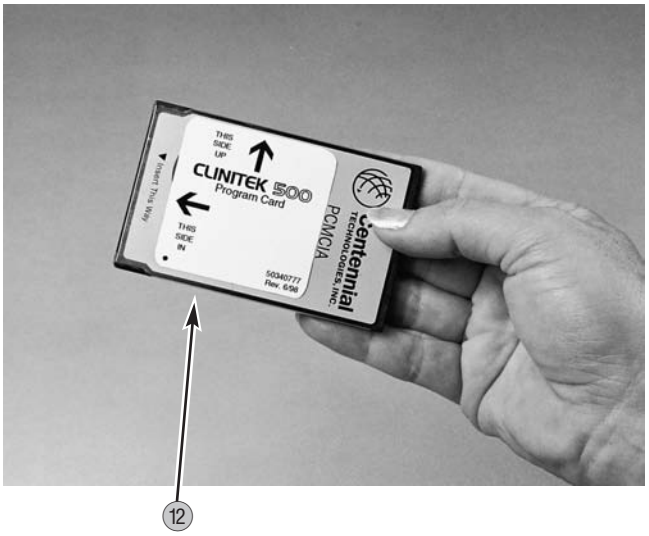


Figure 1-5

The instrument stores the operating parameters, plus up to 500 patient results and 200 control results, in a battery-backed RAM memory. This memory is saved regardless of whether the power is *on* or *off.* The operating parameters (including those selected by the user) are also stored on the program card and can be copied to other CLINITEK 500 instruments.

Optical System

The instrument contains two readheads, each of which contains an incandescent lamp and photodiode pack. When a strip is moved into position under the readhead, the calibration cycle is performed (see "Calibration" next), then the readhead scans the entire length of the strip, measuring the light reflectance of each reagent pad. A portion of the light striking the pad is reflected back to the photodiode pack. The light reflected at specific wavelengths from the test pad is dependent upon the degree of color change in the pad and is directly related to the concentration of the particular constituent in the urine.

The photodiode pack contains four filters, one each at 400–510 nm (blue), 510–586 nm (green), 586–660 nm (red), and 825–855 nm (IR). The light intensity detected by the photodiode pack is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results. The results can be printed by the internal printer; they can also be sent to a computer and/or a form or 80-column printer.

Calibration

Calibration is performed at each readhead immediately before each Reagent Strip is read. The fixed platform contains two white calibration bars that are positioned directly under each readhead. As a strip comes into position under a readhead, the instrument is calibrated for that scanning cycle by reading the calibration bar. The Reagent Strip is then scanned and the data stored in memory.

Specifications

Power Required:
100–240 VAC ±10%, 50–60 Hz

Maximum Power Input:
72 VA

Fuse Rating: (not user-replaceable)
2A, 250 V, 2AG, SB(T)

***Line Leakage Current:**
<0.5 milliamperes in normal condition
<3.5 milliamperes in single fault condition

Heat Output:
Approximately 246 BTU/hour

Dimensions:
Depth — 32.4 cm (12.8 in.)
Width — 37.7 cm (14.8 in.)
Height — 28.2 cm (11.1 in.)

Weight:
7.4 kg (16.3 lb.)

Ambient Operating Temperature Range:
18°C to 30°C (64°F to 86°F)

Ambient Operating Humidity Range:
20% to 80% relative humidity

Optimum Operating Conditions:
22°C to 26°C (72°F to 79°F);
35% to 55% relative humidity
NOTE: Because of the nature of the urobilinogen and leukocyte reagents found on Bayer Reagent Strips, these two results may be decreased at temperatures below 22°C (72°F) and increased at temperatures above 26°C (79°F).

Safety Standards:
The CLINITEK® 500 Urine Chemistry Analyzer (Model 6470) is listed by the Underwriters' Laboratories (UL) and the Canadian Standards Association (CSA) as certified and complies with the safety standards specified in UL 3101 and CSA-C22.2, No. 1010.1. The instrument meets the provisions of the IVD Directive 98/79/EC (Oct./1998) (CE), which includes the EMC Directive 89/336 Amendment 92/31/EEC and the Low Voltage Safety Directive 73/23/EEC.

The safety standards specify that the instrument must operate safely in the following conditions:
- indoor use only
- installation category II (IEC 1010)
- pollution degree 2 (IEC 1010)
- maximum altitude 2000 meters (6560 feet)

Warning:
The instrument is for professional, *in vitro* diagnostic use (IVD) and must be used in the manner specified in the Operating Manual in order to provide the safety and performance standards specified.

Symbols on Back of Analyzer:

	Centronics Port (Parallel) for Printer
	Serial Port (RJ45) for Bar Code Reader
	Not a telephone jack
	Serial Port (RJ45)— not currently active
	Serial Port (EIA-232D) for host computer
SN	Serial Number

ASTM Software Interface:
Conforms to ASTM E 1381-91, "Specification for Low-Level Protocol to Transfer Messages between clinical laboratory instrument and computer systems" and ASTM E 1394-91, "Specification for Transferring Information Between Clinical Instruments and Computer Systems."

*Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL 3101-1, CSA 22.2 No. 1010.1, and IEC 1010-1.

Test	Abbreviation	Units	Reported Results	
			Normal System	Plus System
Glucose	GLU	mg/dL	NEGATIVE 100 250 500 >=1000	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE SMALL MODERATE LARGE	NEGATIVE 1+ 2+ 3+
Ketone	KET	mg/dL	NEGATIVE TRACE 15 40 >=80	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
Occult Blood	BLO		NEGATIVE TRACE-LYSED TRACE-INTACT SMALL MODERATE LARGE	NEGATIVE TRACE-LYSED TRACE-INTACT 1+ 2+ 3+
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	No Difference
Protein	PRO	mg/dL	NEGATIVE TRACE 30 100 >=300	NEGATIVE TRACE 1+ 2+ 3+
Urobilinogen	URO	E.U./dL	0.2 1.0 2.0 4.0 >=8.0	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE TRACE SMALL MODERATE LARGE	NEGATIVE TRACE 1+ 2+ 3+
Color*	COL		YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Clarity† (determined visually)	CLA		CLEAR SL CLOUDY CLOUDY TURBID OTHER	No Difference

*Color may be preceded with "LT." or "DK." when determined by the instrument. If determined visually, default descriptions can be changed by the user; "OTHER" can also be reported.

† Reported results are default descriptions that can be changed by the user.

Shaded areas = default abnormal results

Table 1-1
Traditional Bayer Reagent Strips
ENGLISH — CONV.
Units — Conventional

Test	Abbreviation	Units	Reported Results	
			Normal System	Plus System
Glucose	GLU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE 1+ 2+ 3+	No Difference
Ketone	KET		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
Occult Blood	BLD		NEGATIVE +/− +/− INTACT 1+ 2+ 3+	No Difference
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	No Difference
Protein	PRO		NEGATIVE +/− 1+ 2+ 3+	NEGATIVE TRACE 1+ 2+ 3+
Urobilinogen	UBG	umol/L	3.2 16 33 66 >=131	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Color*	COL		YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Clarity† (determined visually)	CLA		CLEAR SL CLOUDY CLOUDY TURBID OTHER	No Difference

*Color may be preceded with "LT." or "DK." when determined by the instrument. If determined visually, default descriptions can be changed by the user; "OTHER" can also be reported.
† Reported results are default descriptions that can be changed by the user.

Shaded areas = default abnormal results

Table 1-2
Traditional Bayer Reagent Strips
ENGLISH — NORDIC
Units — Nordic Plus System

Test	Abbreviation	Units	Reported Results	
			Normal System	Plus System
Glucose	GLU	mmol/L	NEGATIVE 28 5.5 >=55 14	NEGATIVE 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIVE MODERATE SMALL LARGE	NEGATIVE 2+ 1+ 3+
Ketone	KET	mmol/L	NEGATIVE 3.9 TRACE >=7.8 1.5	NEGATIVE 2+ TRACE 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
Occult Blood	BLD	Ery/uL	NEGATIVE Ca 25 TRACE-LYSED Ca 80 TRACE-INTACT Ca 200	NEGATIVE 1+ TRACE-LYSED 2+ TRACE-INTACT 3+
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 >=9.0	No Difference
Protein	PRO	g/L	NEGATIVE 1.0 TRACE >=3.0 0.3	NEGATIVE 2+ TRACE 3+ 1+
Urobilinogen	UBG	umol/L	3.2 66 16 >=131 33	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU	Leu/uL	NEGATIVE Ca 125 Ca 15 Ca 500 Ca 70	NEGATIVE 2+ TRACE 3+ 1+
Color*	COL		YELLOW GREEN ORANGE BLUE RED BROWN	No Difference
Clarity† (determined visually)	CLA		CLEAR TURBID SL CLOUDY OTHER CLOUDY	No Difference

*Color may be preceded with "LT." or "DK." when determined by the instrument. If determined visually, default descriptions can be changed by the user; "OTHER" can also be reported.

† Reported results are default descriptions that can be changed by the user.

Shaded areas = default abnormal results

Table 1-3
Traditional Bayer Reagent Strips
ENGLISH — S.I.
Units — International (S.I.)

Test	Abbreviation	Units	Printed/Displayed Results	
			Normal System	+/– System
Glucose	GLU	mg/dL	NEGATIVE 100 250 500 >=1000	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE SMALL MODERATE LARGE	NEGATIVE 1+ 2+ 3+
Ketone	KET	mg/dL	NEGATIVE TRACE 15 40 >=80	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
Occult Blood	BLO		NEGATIVE TRACE-LYSED TRACE-INTACT SMALL MODERATE LARGE	NEGATIVE TRACE-LYSED TRACE-INTACT 1+ 2+ 3+
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	No Difference
Urobilinogen	URO	E.U./dL	0.2 1.0 2.0 4.0 >=8.0	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE TRACE SMALL MODERATE LARGE	NEGATIVE TRACE 1+ 2+ 3+
Protein	PRO	mg/dL	NEGATIVE 15 30 100 300	NEGATIVE LOW 1+ 2+ 3+
Creatinine	CRE	mg/dL	10 50 100 200 300	No Difference
Protein-to-Creatinine Ratio	P:C	mg/g	NORMAL DILUTE† NORMAL 150 ABNORMAL 300 ABNORMAL >500 ABNORMAL	No Difference
Color*	COL		YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Clarity** (determined visually)	CLA		CLEAR SL CLOUDY CLOUDY TURBID OTHER	No Difference

† Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.
*Color may be preceded with "LT." or "DK." when determined by the instrument. If determined visually, default descriptions can be changed by the user; "OTHER" can also be reported.
**Reported results are default descriptions that can be changed by the user.

Shaded areas = default abnormal results

Table 1-4
MULTISTIX PRO Reagent Strips
ENGLISH — CONV.
Units — Conventional

Test	Abbreviation	Units	Printed/Displayed Results	
			Normal System	+/– System
Glucose	GLU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin	BIL		NEGATIVE 1+ 2+ 3+	No Difference
Ketone	KET		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity	SG		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
Occult Blood	BLD		NEGATIVE +/– +/– INTACT 1+ 2+ 3+	No Difference
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	No Difference
Urobilinogen	UBG	umol/L	3.2 16 33 66 >=131	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU		NEGATIVE 1+ 2+ 3+ 4+	NEGATIVE TRACE 1+ 2+ 3+
Protein	PRO		NEGATIVE LOW 1+ 2+ 3+	No Difference
Creatinine	CRE	mmol/L	0.9 4.4 8.8 17.7 26.5	No Difference
Protein-to-Creatinine Ratio	P:C	mg/mmol	NORMAL DILUTE† NORMAL 17.0 ABNORMAL 33.9 ABNORMAL >56.6 ABNORMAL	No Difference
Color*	COL		YELLOW ORANGE RED GREEN BLUE BROWN	No Difference
Clarity** (determined visually)	CLA		CLEAR SL CLOUDY CLOUDY TURBID OTHER	No Difference

†Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.

*Color may be preceded with "LT." or "DK." when determined by the instrument. If determined visually, default descriptions can be changed by the user; "OTHER" can also be reported.

**Reported results are default descriptions that can be changed by the user.

Shaded areas = default abnormal results

Table 1-5
MULTISTIX PRO Reagent Strips
ENGLISH — NORDIC
Units — Nordic Plus System

Test	Abbreviation	Units	Printed/Displayed Results	
			Normal System	+/– System
Glucose	GLU	mmol/L	NEGATIVE 28 5.5 >=55 14	NEGATIVE 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIVE MODERATE SMALL LARGE	NEGATIVE 2+ 1+ 3+
Ketone	KET	mmol/L	NEGATIVE 3.9 TRACE >=7.8 1.5	NEGATIVE 2+ TRACE 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
Occult Blood	BLD	Ery/uL	NEGATIVE Ca 25 TRACE-LYSED Ca 80 TRACE-INTACT Ca 200	NEGATIVE 1+ TRACE-LYSED 2+ TRACE-INTACT 3+
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 >=9.0	No Difference
Urobilinogen	UBG	umol/L	3.2 66 16 >=131 33	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Leukocytes	LEU	Leu/uL	NEGATIVE Ca 125 Ca 15 Ca 500 Ca 70	NEGATIVE 2+ TRACE 3+ 1+
Protein	PRO	g/L	NEGATIVE 1.0 0.15 3.0 0.3	NEGATIVE 2+ LOW 3+ 1+
Creatinine	CRE	mmol/L	0.9 17.7 4.4 26.5 8.8	No Difference
Protein-to-Creatinine Ratio	P:C	mg/mmol	NORMAL DILUTE† NORMAL 17.0 ABNORMAL 33.9 ABNORMAL >56.6 ABNORMAL	No Difference
Color*	COL		YELLOW GREEN ORANGE BLUE RED BROWN	No Difference
Clarity** (determined visually)	CLA		CLEAR TURBID SL CLOUDY OTHER CLOUDY	No Difference

†Specimen is too dilute to accurately determine ratio result. Repeat test on new specimen.
*Color may be preceded with "LT." or "DK." when determined by the instrument. If determined visually, default descriptions can be changed by the user; "OTHER" can also be reported.
**Reported results are default descriptions that can be changed by the user.

Shaded areas = default abnormal results

Table 1-6
MULTISTIX PRO Reagent Strips
ENGLISH — S.I.
Units — International (S.I.)

INSTALLATION

General Information

This section provides detailed installation instructions for the CLINITEK® 500 Urine Chemistry Analyzer. The installation steps must be followed correctly to ensure proper installation, operation, and service. Read this Operating Manual carefully before attempting to operate the CLINITEK 500 instrument. Follow all instructions carefully.

The CLINITEK 500 is a precision instrument and must be handled accordingly. Rough handling or dropping of the instrument will disturb internal calibrated optics and electronics and/or cause other damage. Always handle the instrument with care.

Environmental Factors

As with all sensitive electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Temperature should be held relatively constant to obtain the highest degree of operating stability. The ambient temperature range for operating the instrument is 18°C to 30°C (64°F to 86°F); the *optimum* temperature range is 22°C to 26°C (72°F to 79°F). At temperatures under 22°C, urobilinogen and leukocyte results may be decreased, and at temperatures above 26°C, increased. The ambient operating humidity range is 20% to 80% relative humidity.

Place the instrument where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, direct sunlight, ovens, hot plates, open burners, radiators, and dry ice baths. Do not place it on the same bench as a source of vibration, such as a centrifuge. The CLINITEK 500 instrument should not be used in an explosive atmosphere. The bench space should be large enough to allow free air circulation around the instrument (3 inches/7.6 cm on all sides).

Unpacking

1. You should have received two cartons: one carton contains the CLINITEK® 500 instrument and a box of accessory parts; the other (the “Installation Pack”) contains the power cord and operating manual that are appropriate for your country. Carefully remove the contents of each carton. Inspect the shipping cartons, accessory box, and instrument for visible signs of damage. If damage to the instrument exists, immediately file a complaint with the carrier.
2. The following items, shown in Figure 2-1, are packed with the instrument:

   (1) Fixed platform, holddown plate, and waste bin liner
   (2) Moving table (2)
   (3) Printer paper
   (4) Push bar (2)
   (5) Program card
   (6) Holddown plate (extra)

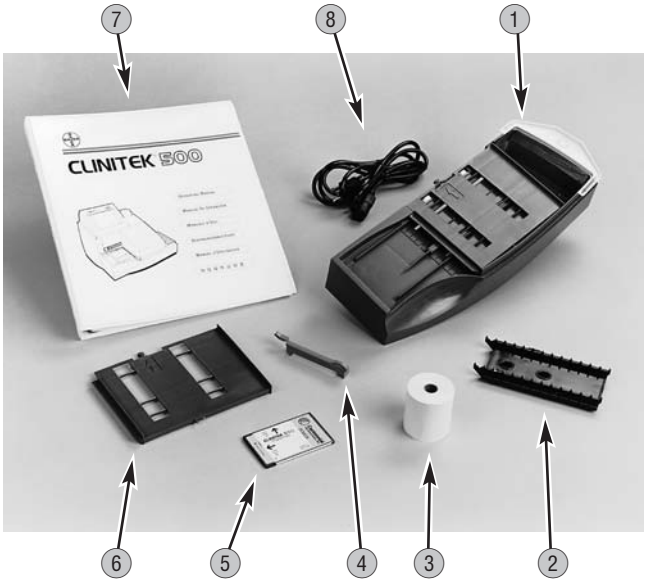


Figure 2-1

The remaining items shown in Figure 2-1 are packed in the Installation Pack and shipped in a separate container from the instrument:

⑦ Operating manual: Binder and manual pages
(Manual pages may be supplied separately by your Bayer representative. Depending on the language of the operating manual you have received, there may also be a Warranty Registration Card and/or a Customer Information Card.)

⑧ Power cord

Make sure all these items have been included with your instrument, and keep them for future use.

3. After the instrument has been unpacked, place it on a firm, level work surface in the designated work area. The instrument should *appear* level, both side to side and front to back. The back and sides of the instrument should be at least 3 inches from an adjacent wall or instrument.

   NOTE: Retain the CLINITEK 500 shipping carton and packing for at least several weeks. If the instrument ever needs to be shipped, the shipping carton will afford the best protection against damage.

4. Locate the piece of foam packing that is under the read area cover. Gently pull down and forward on the foam to remove it (Figure 2-2).

   IMPORTANT: Be sure to remove the foam before continuing!

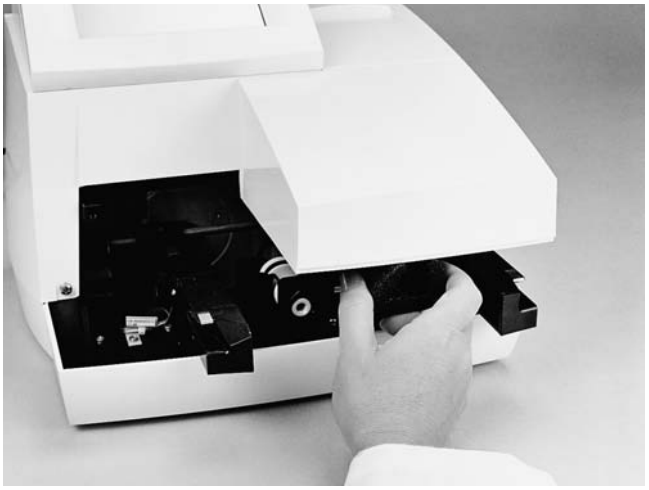


Figure 2-2

5. If you have not already done so, insert the pages of your Operating Manual into the binder.

Instrument Setup

1. Ensure that the instrument power switch is in the OFF ("○") position. Then plug the instrument line cord into the instrument and into an appropriate grounded AC electrical outlet.
2. Locate the bar-coded serial number, which is found inside the instrument near the front left corner (Figure 2-3). Write the installation date and serial number in the spaces provided in the "Preservice Checklist" in Section 8 and on the Manufacturer's Warranty Page that is found at the end of this manual (contact your Bayer representative for your warranty information if this page is not included in your manual).

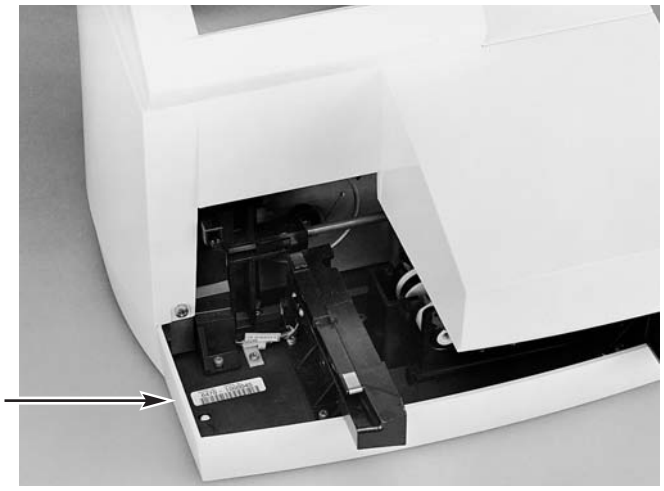


Figure 2-3

3. If a Warranty Registration Card is found at the front of your manual, write the installation date and instrument serial number on this card. After the instrument has been successfully installed, completely fill out the Warranty Registration Card and mail.

4. Install the moving table as follows:
   a. Hold the table with the small rectangular tab facing to the back.
   b. Align the two grooves on the bottom of the table with the edges of the platform on which the table rests (Figure 2-4).

Figure 2-4

   c. Gently push the table in as far as it will go. It must be pushed past a detent in order to be correctly in position.
5. Next, install the fixed platform. (The holddown should already be securely installed onto the platform. If it is not installed, or is loose, refer to Section 5, "Daily Cleaning," Step 11-a, for directions on installing the holddown.) Align the two grooves on the bottom of the platform with the arms extending from the instrument, as shown in Figure 2-5. (The ledges on the left and right sides of the holddown align just outside the read area cover, and the top edge of the platform aligns just under the cover.) Gently push the platform in **as far as it will go.** (It must be pushed past a slight detent to be correctly positioned.)

CAUTION: If the platform does not push in at least halfway with only very gentle pressure, do not force it! Ensure that the moving table is correctly positioned and attempt to reinstall the platform.

NOTE: With the initial installation, you may need to use firm pressure to push the platform the final ½ inch (1.3 cm). If the platform is not fully seated, or if it is slightly crooked, the strips may jam as they are pushed along the platform.

Figure 2-5

6. Hold the push bar by its indented end and, with this end slightly upward, insert the peg on the other end of the bar into the hole in the pusher mechanism (Figure 2-6). Lower the push bar into place.

Figure 2-6

7. Hold the program card with the label facing forward and the arrows pointing in and up. Insert the card into the card receptacle (Figure 2-7) and press it in **firmly** until the button above the receptacle is pushed out. When properly inserted, the edge of the card will be flush with the side of the instrument.

Figure 2-7

8. Install a roll of printer paper and re-install the printer cover as follows:
   a. Notice the large tab on the back side of the instrument that secures the cover in place (Figure 2-8). Press in firmly on the bottom edge of the tab and lift the cover off.

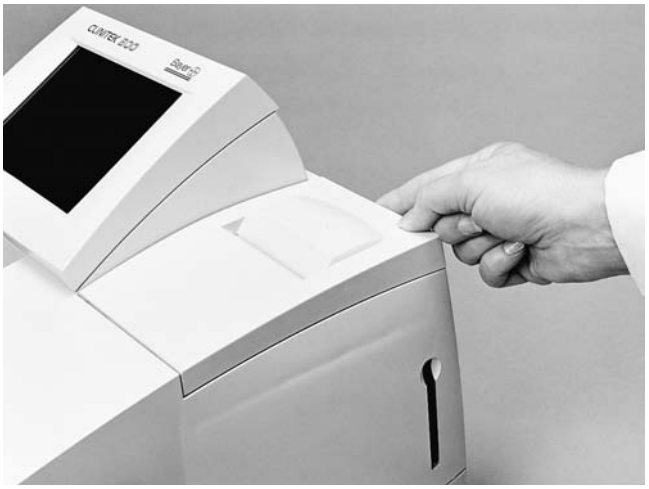


Figure 2-8

   b. Obtain a new roll of paper; unroll several inches and trim the end into a long “V”. Hold the roll just above the printer, with the paper unrolling from underneath. Feed the end of the paper under the roller, then rotate the paper advance wheel in a clockwise direction (toward the back) until several inches of paper are exposed above the printer (Figure 2-9).

Figure 2-9

c. Set the paper into position behind the printer. Then, place the front tabs of the cover into their slots and feed the end of the paper through the opening in the cover. Snap the cover into place.

9. If not already installed, place a liner into the waste bin (Figure 2-10).

Figure 2-10

Interfacing to a Printer

The CLINITEK 500 can be interfaced to most 80-column, continuous feed printers or to the CLINITEK® Form Printer via the printer (parallel) port that is found on the rear of the instrument.

1. Some printers may include an interface cable that is appropriate for use; if not, you will need to obtain the cable separately. Refer to Appendix CPI, "COMPUTER AND PRINTER INTERFACE," for the pin specifications for the male connector. The other end of the cable will be dependent upon the particular printer. Appropriate cables are available at most retail computer stores.
2. Connect the appropriate end of the interface cable to the printer port on the CLINITEK 500 (labeled "⎚") (see (1) Figure 2-11 for location); connect the other end to the printer.

Figure 2-11

3. Carefully read the operating manual that accompanies the printer and become familiar with its operation before using.

Interfacing to a Computer

The CLINITEK 500 can also be interfaced to a host computer or LIS (Laboratory Information System) via the serial port and a Null modem cable. The cable requirements for interfacing to a computer are found in Appendix CPI, "COMPUTER AND PRINTER INTERFACE." Connect the appropriate end of the interface cable to the port on the CLINITEK 500 labeled "10101" (2 in Figure 2-11); connect the other end to the appropriate port on the computer, following the instructions given with the computer.

Interfacing to a Bar Code Reader

A Handheld Bar Code Reader (Product No. 6469) is available for use with the CLINITEK 500 Analyzer. It is connected through the RJ45 interface port (labeled "|||||") (3 in Figure 2-11). Refer to Appendix BCR that is included with the Handheld Reader for complete information.

Initial Instrument Check

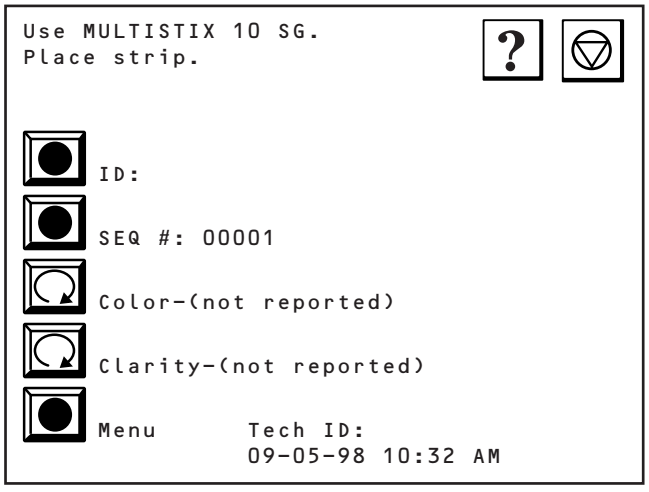
After the CLINITEK 500 has been properly installed, perform the following initial instrument check. The actions that should occur during instrument operation are described in this check. If problems occur during this procedure or if an error message is displayed, refer to Section 8, TROUBLESHOOTING AND SERVICE.

1. Press the power switch to the ON ("—") position. The push bar will move and the display will be illuminated, first showing the instrument name and a series of dots while the system initializes. It then changes to the title screen, which shows the software version numbers, along with the instrument name and copyright information. The system then does several internal checks and procedures. Each check and its status is displayed while the testing is being performed. Verify that the fan is *on* by holding your hand near the fan cover located at the upper left corner on the rear of the instrument.

   NOTE: If an error occurs, a message will be displayed that instructs you either to turn the power *off,* then back *on* after several seconds, or to contact customer service (see Section 8, TROUBLESHOOTING AND SERVICE).

2. The display changes to the **Ready/Run** screen, which is the starting point for testing and selecting the options that will customize the instrument to meet your laboratory's needs. The screen also shows the name of the Bayer Reagent Strip for Urinalysis that is programmed for use on the instrument (for example, "MULTISTIX 10 SG").

   The **Ready/Run** screen will be displayed as, for example:



Verify that the Reagent Strip name being displayed agrees with the strip to be used. **Use of any other strip will cause erroneous results.** If the strip names do not agree, the selected strip must be changed before beginning testing. The strip is selected through the **Setup** Routine, described in Section 3.

3. Completely immerse a Bayer Reagent Strip into a negative control urine, such as CHEK-STIX® Negative Control Strips solution. Immediately remove the strip. While removing, slowly run the edge of the entire length of the Reagent Strip against the side of the tube to remove excess urine. Do *not* blot the edge of the strip against a paper towel, as doing so may affect test results.
4. Place the Reagent Strip, **with reagent areas up,** onto the strip loading station (Figure 2-12). The push bar should begin moving almost immediately, pushing the strip into the read area, and the keys shown on the display will be shown as dimmed (partially lit) symbols.

Figure 2-12

5. After the strip has been read, the test results will be printed by the internal printer. The instrument should produce a result for each reagent area that is within the limits given in the package insert for the control urine.
6. If the instrument does not perform as expected, or if the printed results do not agree with the expected values, refer to Section 8, TROUBLESHOOTING AND SERVICE.
7. Before beginning normal instrument use, carefully review the following sections to become familiar with the instrument software, operating techniques, and cleaning requirements:
   Section 3 SELECTING YOUR OPTIONS
   Section 4 INSTRUMENT OPERATION
   Section 5 CARE OF THE INSTRUMENT
8. With satisfactory completion of the initial instrument check, the CLINITEK 500 Analyzer is ready for routine testing. Enter the **Setup** Routine and follow the displayed prompts to customize the software for your laboratory. Refer to Section 3 for complete information.

SELECTING YOUR OPTIONS

General Information

All interaction between the operator and the CLINITEK® 500 Analyzer is through the touch screen. Messages, options, and requests for information are displayed, along with "keys" that can be touched to respond in the desired manner. A light touch is all that is necessary to activate the key. **Do not use anything hard or pointed on the touch screen. (If a key does not respond, press it for a slightly *longer* time, rather than harder.)**

- **If an option key is active,** the key symbol is displayed fully lit. Whenever an active key is touched, you will see a change either in the display or in the instrument operation.
- **If an option key is *not* active,** the key symbol is dimmed and a unique double tone will sound if it is touched.

Several keys are displayed on various screens, and they will always have the same function whenever they are displayed:

Return to Ready/ Run

Returns the screen to the **Ready/Run** screen; **must** be touched when exiting the **Setup** Routine in order to save the changes made. If this key is touched from a screen in which data is requested and ↵ (**Enter**) was not touched first, any data that was entered will **NOT** be saved. This key appears on most screens, always in the upper right corner.

Stop Run

Cancels the run or the last strip. If the run is cancelled, all strips on the platform are immediately moved to the waste bin and no results are reported for them. This key is displayed on the **Run** screen and becomes active (fully lit) as soon as the first strip in a run is detected. It is located in the upper right corner, in place of the ⏏ key.

Help

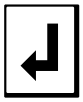
Touching this key causes a **Help** screen to be displayed that has information pertaining to the screen from which the key was touched. Touch the ◀ key from the **Help** screen to return to the previous screen. The key is not displayed on all screens but, when displayed, always appears to the left of the ⏏ (**Return to Ready**) or ▽ (**Stop Run**) key.

Next Screen

Changes the display to the next screen in a series. This key is displayed only if there are additional screens to be viewed and always appears in the lower right corner.

Previous Screen

Changes the display back to the previous screen in a series. This key is displayed only if there are earlier screens in the series to be viewed and always appears in the lower right corner, immediately above the ▶ key (**Next Screen**) location.



Enter

Must be touched in order to accept data that has been entered, such as ID and sequence numbers, date, and time. *If the screen is exited without first touching ↵, the newly entered data is not saved;* any data previously in memory is retained.

Move Right

Moves the cursor one space to the right from its current position. If the cursor is at its right-most position, touching this key has no effect. Moving the cursor does not erase any characters; new characters can be entered directly over the incorrect characters.

Move Left

Moves the cursor one space to the left. The character at the current position is usually erased before the cursor is moved to the left. If the cursor is at its left-most position, the cursor does not move. Exception: if this key is displayed in conjunction with the ➔ key (**Move Right**), the existing characters are not erased as the cursor is moved.

SELECTING YOUR OPTIONS

Move Up

Move Up displays the previous stored result or entry in descending order (lower sequence number). **Move Up 10** displays the record stored ten positions lower than the currently displayed record; if there are fewer than ten lower-numbered results, the oldest stored result or entry is displayed.

Move Up 10

Move Down

Move Down displays the next stored result or entry in ascending order (higher sequence number). **Move Down 10** displays the record stored ten positions higher than the currently displayed record; if there are fewer than ten higher-numbered results, the most recently stored result or entry is displayed.

Move Down 10

Plus

Plus increases the displayed number by 1 each time the key is touched.

Minus

Minus decreases the displayed number by 1 each time the key is touched.

Alphabet

Changes the display to the full alphabet to allow entry of alphabetic characters in, for example, a specimen ID, Tech ID, or control lot number.

Delete

Allows a single record or all records shown on the screen to be deleted. A second screen is always displayed, from which you can select how many records are to be deleted (one or all) or to confirm that all records are to be deleted.

Print

Allows one or more records from a displayed list to be printed.

Resend

Allows one or more records from a displayed list to be resent to a computer.

In addition to the function keys, three different types of keys will be displayed in order to assist the operator in selecting the desired option in various menus. If the key is displayed as a fully lit symbol, the key can be touched to select the option or cycle through the list of options. If the key is displayed as a dimmed symbol, the option is not available for selection.

Action Key

Touching an action key selects the option described next to the key. The display always changes to another screen, either to start the selected routine or to display an appropriate screen that defines how the selected option will work.

Cycle Key

The cycle key is used when several options are available. Each time the key is touched, a different option is displayed for selection. When the desired option is displayed, the selection is complete.

Selection Key

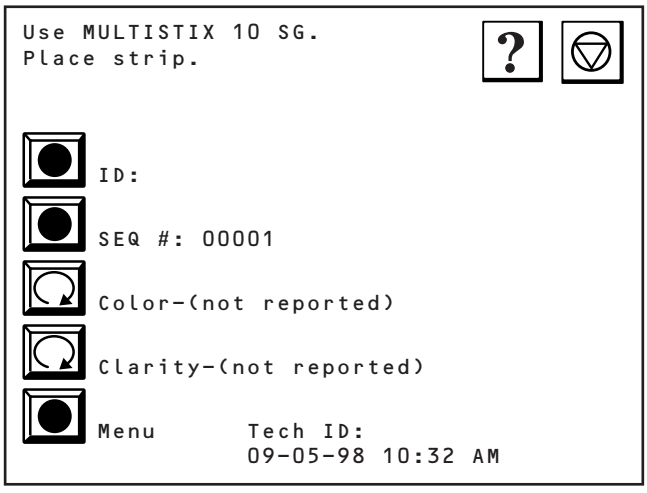
Selection keys are used to select or reject the use of an option. If a check mark (✓) appears in the key symbol, the option is selected (turned *on*); if the key symbol is empty, the option is not selected (turned *off*).

Setup Routine

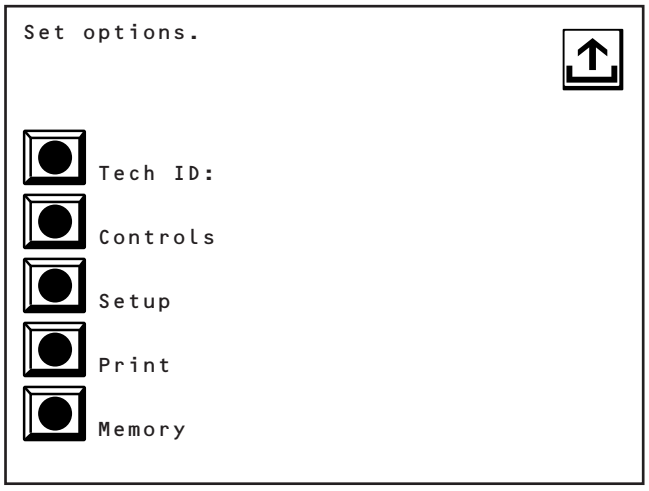
The **Setup** Routine should be entered when the instrument is initially installed to select the various parameters desired by your laboratory. Thereafter, this routine will probably be entered infrequently. Several of the options can be accessed freely; for example, the date and time can be changed through this routine, the computer port turned *on* or *off,* and the printer selected. Access to additional options can be protected through the use of a password.

Table 3-1, at the end of this section, shows a flow chart of the Menu Option and the **Setup** Routine, which is selected from the Menu Option.

Enter the **Setup** Routine from the **Ready/Run** screen, shown below; for example:



Touch the key symbol (▣) next to the word **Menu** to display the Option Menu; for example:

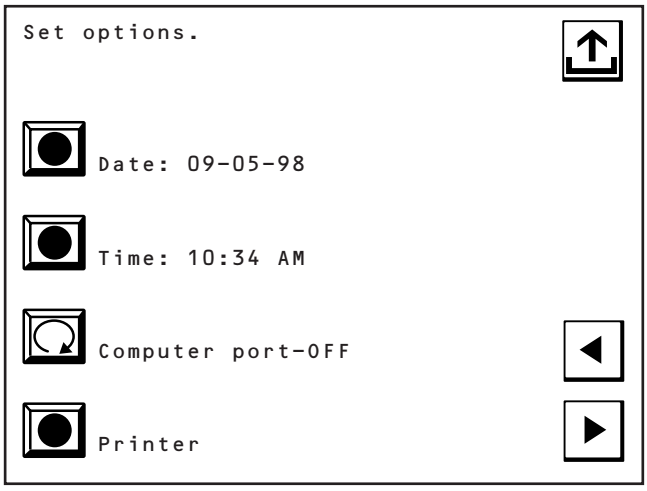


Touch the **Setup** key symbol from the Option Menu to enter the **Setup** Routine.

NOTE: Memory may be erased if a change is made to any of several **Setup** options. **All** results and loadlisted ID numbers stored in memory will be deleted when the change is made. A warning screen will be displayed first, and you will be given the option of not making the change to the **Setup** option, saving the stored results and numbers. Be sure all patient and control results have been printed and/or transferred and that a loadlist is not stored in memory before making the changes.

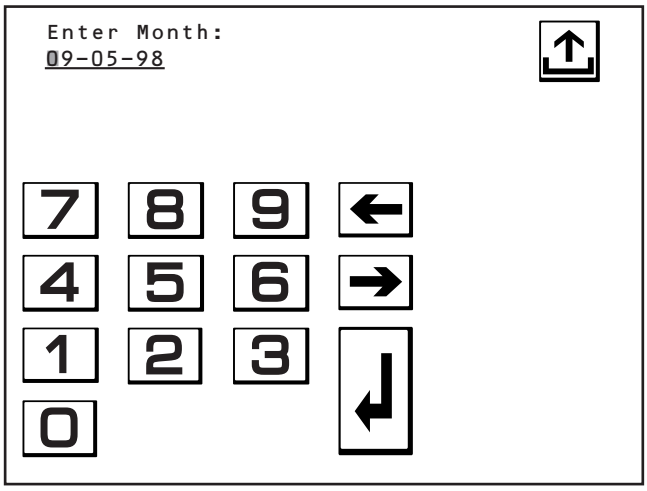
A. Setup Menu #1

The first **Setup** menu is displayed; for example:



Touch the key symbol that appears next to the option you want to change. Each option is described below.

1. **Date:**
   a. When the **Date** key is touched, the display changes to show the current date and a numeric keypad by which the date can be changed (the date format and separator can be changed through Setup Menu #3, Step D). For example:



   b. Enter the correct date by touching the proper numeric keys, or touch the arrow keys to move the cursor to the digit that needs to be changed and enter the correct number. The message will change as you move from one part of the date to the next, showing the prompt, for example, "Enter day," then "Enter year." Be sure to enter the leading "0" where needed.
   c. When the date has been entered, touch ↵. A message will be displayed if an invalid date is entered; be sure the date has been entered in the order shown on the prompts. If the date is valid, the display returns to the first **Setup** menu.

2. **Time:**
   a. When the **Time** key is touched, the display changes to show the current time (in the selected format) and the numeric keypad by which the time can be changed, similar to that displayed for changing the date. (The time format and separator can be changed through Setup Menu #3, Step D.)
   b. Enter the appropriate digits by touching the proper numeric keys and/or touch the arrow keys to move the cursor to the appropriate digit that needs to be changed. The message will change as you move from one part of the time to the next, showing the prompts "Enter hour" and "Enter minutes." Be sure to enter the leading "0" where needed.
   c. If the time format is "12 Hour," touch the **AM/PM** cycle key to change from AM to PM or vice-versa. (If the time format is "24 Hour," the **AM/PM** cycle key is not active.)
   d. When the time has been entered, touch ↵. A message will be displayed if an invalid time is entered. If the time is valid, the display returns to the first **Setup** menu.

3. **Computer port:**
   Touch the **Computer port** cycle key to change the selection between OFF and ON. Depending upon the selection made, results can be transferred to a computer. The specifications for the computer port are selected later in the **Setup** Routine.

4. **Printer:**
   a. Touch the **Printer** key symbol to change several printer options:
      i. **Internal:** The internal printer can be used to print patient results, with several options for the format, or it can be turned *off.* Touch the **Internal** cycle key to select the desired option of OFF or ON, with 2, 6, or 12 blank lines between patient result sets.

         NOTE: There are always two blank lines between control result sets.

      ii. **Custom header:** When "12 blank lines between patient result sets" is selected for the internal printer, a header is printed at the end of each printed report obtained through that printer. The default header is "MICROSCOPICS"; this can be customized, if desired, or changed to contain all blanks if you do not want a header at all.

         When the **Custom header** option key is touched, an alphabetic keyboard is displayed, from which up to 24 letters and spaces can be entered. Touch ↵ when the entry is correct to store it in memory and return the display to the Printer Option menu.

      iii. **External:** An external printer can be used instead of, or in addition to, the internal printer. This printer can be a form or 80-column, continuous-page printer. Touch the **External** cycle key to change the selection between "OFF"; "ON, 80 column"; "ON, Form Printer 1"; "ON, Form Printer 2"; and "ON, Form Printer 3."

         NOTE 1: Select "ON, Form Printer 1" if you are using the Printer Products Form Printer or if you want to use an 80-column printer but print a single record on each page. If using the CLINITEK® Form Printer, select "ON, Form Printer 2" as the external printer option (see NOTE 2 below). The "Form Printer 3" option is appropriate for use with the Star Form Printer, available from Bayer Corporation as Product No. 5257. If you are unsure of which format to use, print a record using each option to determine which one provides the best placement of the printed results on the form and that works appropriately with your form printer. See Appendix CPI, "Cable and Pin Specifications — Parallel Port" for additional information on the three formats.

         NOTE 2: If using the CLINITEK Form Printer, you must also set the Mode Switches on the printer to "Computer" (both DS1-1 and DS1-2 switches DOWN). For further information, refer to Section 5 in the Operating Manual for the CLINITEK Form Printer.

   b. When all printer options have been selected, touch ◀ to return to the first **Setup** menu.

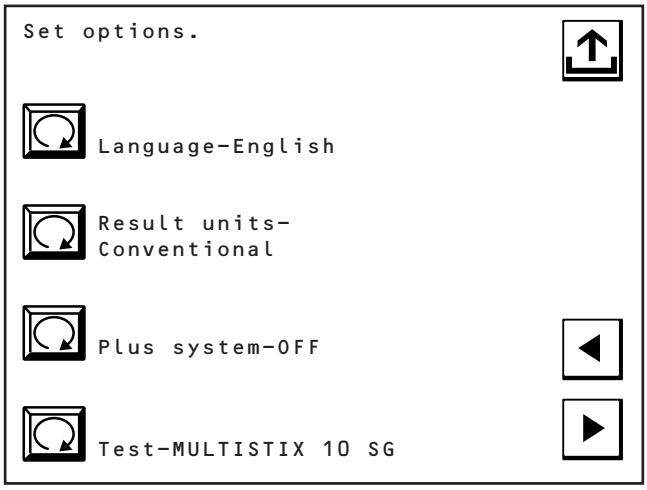
B. Password Screen

If all selections have been completed from the first **Setup** menu, touch ▶ to move either to the password screen or directly to the second **Setup** menu, depending upon whether password protection of the remaining screens has been selected (see Step I-3 later in this section).

If password protection has not been requested, the display changes as described in Step C next. If a password is being used, a numeric screen is displayed from which the password can be entered. Touch ↵ when the password has been entered. If it has been entered correctly, the display changes as described in Step C. If it is incorrect, a message is displayed and you can enter the code again.

C. Setup Menu #2

The second menu of the **Setup** Routine is displayed as, for example:



1. Each of the menu options feature cycle keys that, when touched, display the next in a series of options for the menu item.
   - **Language:** All screens will be displayed in the language that is selected. Also, the default selection for several other options may change, depending upon the language selected (for example, the date and time formats, test name [Reagent Strip type], and reporting of color).
   - **Result units:** Several of the languages have options for the units in which results are displayed. See the Tables of Results at the end of Section 1 for the results that are displayed and printed for each option. (As with Language, the default selection for several other options may change, depending upon the result units selected.)
   - **Plus system:** Results can be displayed and printed in the Plus system (which uses "+" symbols) rather than in clinical units such as mg/dL.
   - **Test:** Many configurations of Bayer Reagent Strips can be used on the CLINITEK 500 Analyzer. However, not all configurations are available in every country. **Be sure the Reagent Strip selected agrees with the name of the Bayer Reagent Strip being used.**
2. Touch the cycle keys as needed to obtain the desired option. The table below lists the options that are available for each of the cycle keys:

Language:	**Result units:**	**Plus system:**
English Français Deutsch Italiano Kanji Español Português Chinese	(with English, Français, Deutsch, and Chinese) Conventional Nordic* S.I. *English only	OFF ON

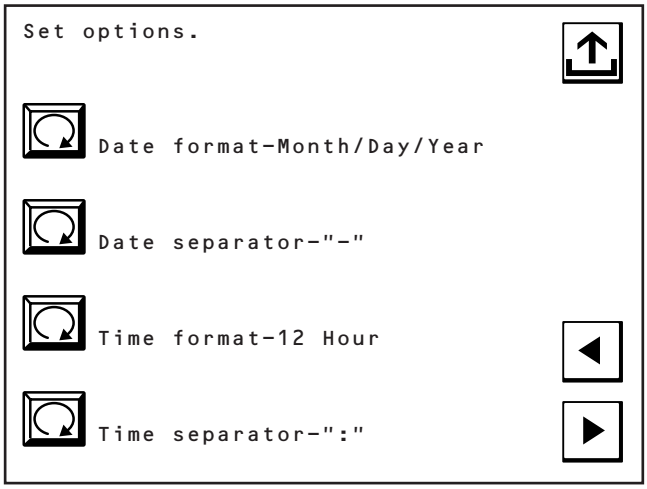
Test:†

MULTISTIX® 10 SG	COMBISTIX® SG - LONG
MULTISTIX® 9 SG	HEMA-COMBISTIX® - LONG
MULTISTIX® 8 SG	URISTIX® - LONG
MULTISTIX® SG	LIFESTIX®
MULTISTIX® SG L	MULTISTIX PRO® 11
MULTISTIX®	MULTISTIX PRO® 10LB
N-MULTISTIX® SG	MULTISTIX PRO® 10LS
NEPHROSTIX® L	MULTISTIX PRO® 10SB
URO-HEMACOMBISTIX® SG L	MULTISTIX PRO® 10
URO-LABSTIX® SG	MULTISTIX PRO® 7G
URO-LABSTIX® SG L	MULTISTIX PRO® 7PH
MULTISTIX® 9	MULTISTIX PRO® 6B
URO-HEMACOMBISTIX®	MULTISTIX PRO® 6K
URO-LABSTIX®	

†Not all Reagent Strips are available in all countries.

D. Setup Menu #3

When all selections have been made from the second menu, touch ▶ to move to the third menu in the **Setup** Routine; for example:



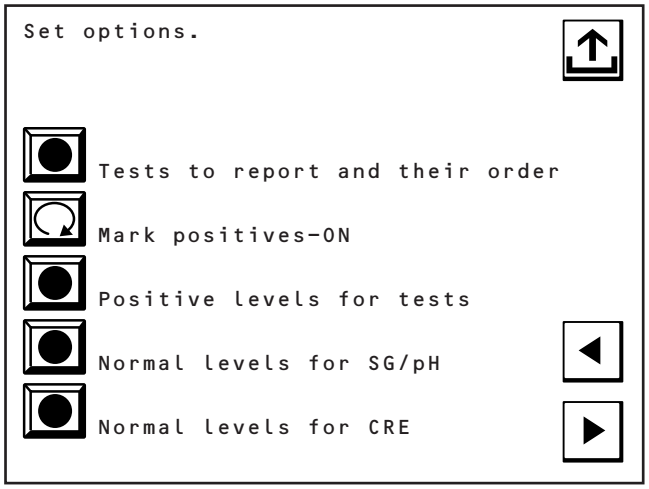
As with the previous menu, each of the options feature cycle keys. The available options are:

Date format:	**Date separator:**
Month/Day/Year Day/Month/Year Year/Month/Day	" – " " . " " / "
Time format:	**Time separator:**
12 Hour 24 Hour	" : " " , " " . "

Touch the keys as needed to select the desired options.

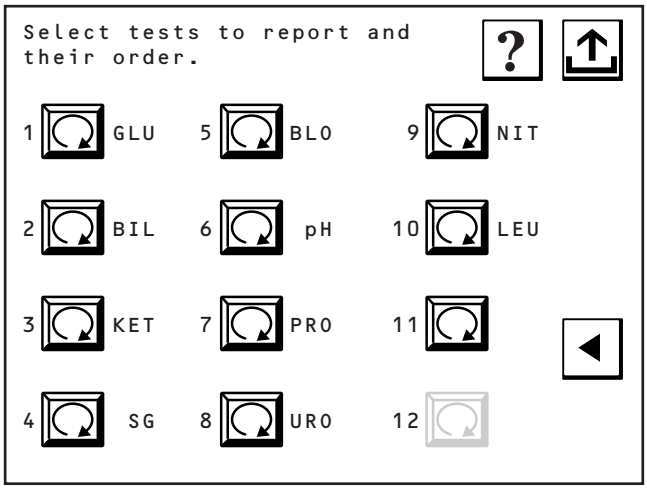
E. Setup Menu #4

When all selections have been made from the third menu, touch ▶ to move to the next menu in the **Setup** Routine; for example:



1. **Tests to report and their order:**
   Even if an analyte or physical parameter is tested on the CLINITEK 500 Analyzer, you may choose to not report it; you can also select the order in which the tests are reported. If "English S.I." is the selected language, color is also included as the last test; if not already selected, it can be added to the end of the list. You can also choose to include clarity (determined visually) as a reported result through this menu option.

   When the action key is touched, the display will show a series of cycle keys, labeled 1 through 12. For example:



The number of fully lit keys will equal the number of tests being reported, plus one, with exception of the P:C ratio (see Step 1-a below). Each time a new test is added to the list, the next key becomes fully lit until the number equals the number of tests on the selected Bayer Reagent Strip plus two (color and clarity). (Note that only one protein result is reported from the protein–low and protein–high tests when using MULTISTIX PRO® Reagent Strips.) If the tests being reported and their order are all correct, touch the ◀ key to return to the previous menu. If you want to make changes, proceed as follows:

a. **P:C Ratio:** If you are using a MULTISTIX PRO Reagent Strip, the instrument will calculate a protein-to-creatinine (P:C) ratio. The P:C ratio will always be reported and will always appear in the *last* position of the reported results. Its order cannot be changed and, therefore, this test will not appear on the screen for selecting the tests to report.

b. **Selecting Color/Clarity:** If color and/or clarity are not listed, you can quickly and easily add one or both to the list by touching the last *fully lit* key until the desired test name (COL or CLA) is shown. Touch the next key (which is now fully lit) to add the other test name. Color and clarity will be reported in the last two positions if you make no further changes.

c. If you want to change the order in which tests are reported, touch the cycle key at the first position you want to change. Any test(s) not already listed will be displayed first; then a blank will be displayed and all tests from that position on will be erased and must be re-entered. Touch the cycle key until the desired test is displayed. As each test is selected, the next test in the list will be the first test displayed for the following position.

d. Select the desired test for each of the remaining positions. If you want to remove a test from the reporting order (not reported), select the tests you do want to report and leave a blank description in the **final** position.

e. When the correct tests and order are displayed, touch ◀.

2. **Mark positives:**
All positive results can be marked with an asterisk (*) in the displayed and printed report, as well as in the data transferred to a computer. Touch the cycle key to change the selection between ON and OFF.

NOTE: If this option is OFF, you will be unable to make selections for several other options (see Steps E-3, E-4, E-5, G-1, G-2, and/or G-3 later in this section).

3. **Positive levels for tests:**
The lowest result that is considered to be positive can be changed from the default levels, if desired, for each of the chemistry tests. (The physical parameters of SG, pH, color, and clarity are changed in other menu options.) If "Mark positives" (Step E-2 previously) is ON, all positive results are marked with an asterisk (*) in the displayed and printed report, as well as in the data transferred to a host computer. These levels are also used by the Analyzer to determine which specimens meet the criteria for the confirmatory and microscopic reports. When the action key is touched, the display shows the lowest positive level for the first four tests selected in the previous screen (**Tests to report**).

If Protein has been selected as a reported test, the first screen shows three different options for Protein, one for each of the different groups of Bayer Reagent Strips that can be used on the instrument. The reported results for protein vary slightly, depending upon which group of Reagent Strips is used (see the Tables of Results in Section 1). The first option is for the traditional Bayer Reagent Strips (e.g., MULTISTIX 10 SG); the second is for MULTISTIX PRO 6B and MULTISTIX PRO 6K strips (not available in all countries); and the third is for all other MULTISTIX PRO strips. By selecting the first positive level for each group, you can then select a different strip for use in testing (Step C-1 previously) without having to change the selection of the first positive level of the protein test.

NOTE: Nitrite is not listed, since it has only one positive level. Also, the P:C ratio is not listed, since these results already include a description of "NORMAL" or "ABNORMAL."

a. Touch the cycle key for the test you want to change, repeating until the desired level is displayed.

b. When all tests on the first screen are correct, touch ▶ to display the remaining tests (if additional tests are reported).

c. When all tests are correctly set, touch ◀ as needed to return to the previous option menu.

4. **Normal levels for SG/pH:**
The lower and upper limits of the range considered to be normal for SG and pH can be selected by touching this key. Each limit is set separately; however, the upper limit must be higher than or equal to the lower limit.

a. Touch the **+** or **—** keys next to the limit you want to change to raise or lower the displayed number. With each touch, the number will change by one reporting level until it is equal to the opposite limit or is at the highest or lowest reporting level.

b. When all limits have been set, touch ◀ to return to the previous option menu.

NOTE: This option can be selected only if "Mark positives" (Step E-2 previously) is ON.

5. **Normal levels for CRE:**
As with SG and pH, the lower and upper limits of the normal range for creatinine can be selected by touching this key. However, you must be using a MULTISTIX PRO Reagent Strip in order for this option to be active. Each limit is set separately, but the upper limit must be equal to or higher than the lower limit.

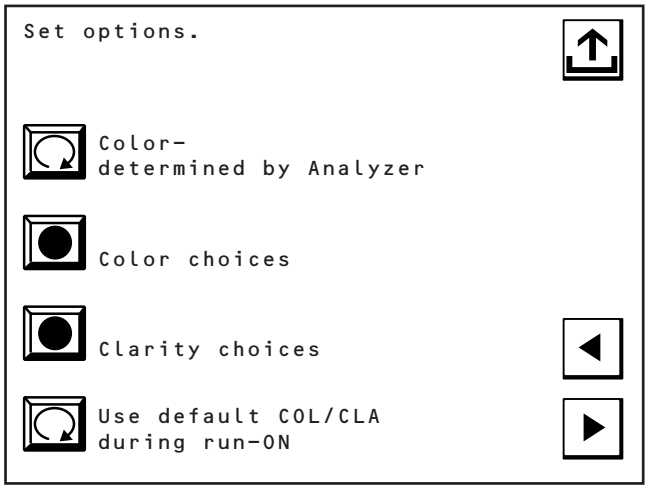
a. Touch the **+** or **—** keys next to the limit you want to change to raise or lower the displayed number. With each touch, the number will change by one reporting level until it is equal to the opposite limit or is at the highest or lowest reporting level.

b. When both limits have been set, touch ◀ to return to the previous option menu.

NOTE: This option can be selected only if "Mark positives" (Step E-2 previously) is ON.

F. Setup Menu #5

When all options on the fourth menu have been correctly set, touch ▶ to proceed to the next **Setup** menu; for example:



1. **Color:**
   If color has been selected as one of the tests to be reported (in Step E-1 previously), it can either be determined by the CLINITEK 500 Analyzer or be entered manually by the technician from a visual determination. Touch the cycle key to select the desired option ("determined by Analyzer" or "entered by tech"). If "entered by tech" is selected, the color can be entered as part of a loadlist and/or just before each specimen is tested.

   NOTE: Color can be determined by the Analyzer only if the Bayer Reagent Strip being used contains the leukocyte test. Results reported by the Analyzer may be different from the color seen visually. This is because of the inherent differences between the human eye and the optical system of the instrument.

2. **Color choices:**
   If the color option above is "entered by tech," you can specify up to seven options from which to select the specimen color. Any of the default options can be removed from the reporting list; the name of each option can also be customized.

   a. The first four default colors will be displayed initially (YELLOW, ORANGE, RED, GREEN). If the selection key contains a check mark, the color is included in the list; touching the key removes the check, deleting the option from the list. (The first option must be selected and is always shown as a dimmed key.)

   b. The color name can be changed by touching the word describing the color. The display will change to the alphabetic keyboard. Use the ← key to erase the existing name, if necessary, and enter the new name of up to 15 letters and spaces. Touch ↵ when done to return to the previous screen.

   c. When finished with the first four colors, touch ▶ to display the last three default colors (BLUE, BROWN, and OTHER). Remove or add color options, or change their descriptions, as needed, then touch ◀ as needed to return to the previous option menu.

3. **Clarity choices:**
   If clarity is selected as a reported result (Step E-1), it can be determined visually only. You can specify up to five options from which to select the specimen clarity. As with **Color choices** previously, any of the default options can be removed from the reporting list and the name of each option can be customized.

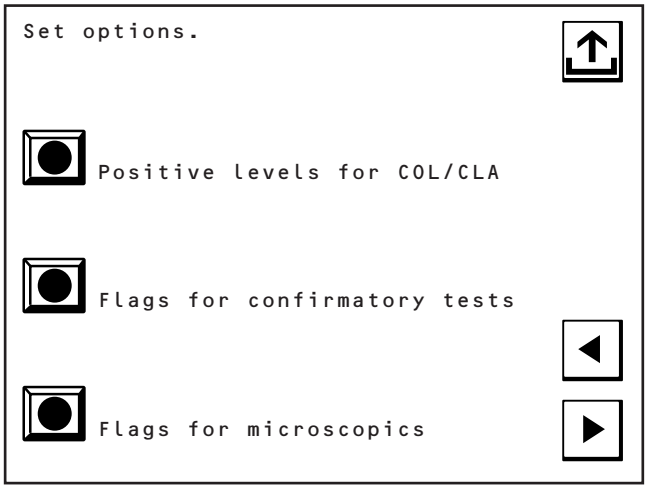
   a. The first three choices are shown initially (CLEAR, SL CLOUDY, and CLOUDY); the second screen displays two additional options (TURBID and OTHER). Remove or add options, or change their descriptions, as needed, on each of the two screens, in the same manner as in Step F-2 previously.

   b. Touch ◀ as needed to return to the previous option menu.

4. **Use default COL/CLA during run:**
   The first reporting value for color and/or clarity can be displayed as the default value by setting this option to ON. It is available only if color is being reported and is "entered by tech" and/or clarity is being reported. Each default value can then be changed, if needed, prior to testing the specimen. If this option is set to OFF, the description lines for color and/or clarity are blank (no default value displayed) until the cycle key is touched. Use of the default value can be turned ON and OFF by touching the cycle key.

G. Setup Menu #6

Touch ▶ to move to the next **Setup** menu when all selections have been made on the fifth menu. The new menu is displayed as, for example:



1. **Positive levels for COL/CLA:**
   If either color or clarity was selected as a test to be reported, the first result that is considered to be positive can be selected. As with the chemistry tests and if "Mark positives" (Step E-2 previously) is ON, these levels are used by the Analyzer to determine which specimens meet the criteria for the confirmatory and microscopic reports. Positive results are also marked with an asterisk (*) in the displayed and printed report and in the data transferred to a host computer. When the selection key is touched, the display shows the first level that is considered to be positive.

   a. Touch the appropriate cycle key until the display shows the first level you want to have marked as positive. All results later in the list are also called positive. If you have not changed or removed any of the descriptions (Step F-2), the options are:

Color:		Clarity:	
YELLOW	GREEN	CLEAR	TURBID
ORANGE	BLUE	SL CLOUDY	OTHER
RED	BROWN	CLOUDY	
	*OTHER		

*If visually determined

   b. Touch ◀ when both selections have been made to return to the previous option menu.

2. **Flags for confirmatory tests:**
   Up to five tests (of those to be reported) can be selected for the confirmatory report. If a specimen has a positive result for any of the tests selected, **and** if "Mark positives" is ON (see Step E-2), the record will be flagged and can be recalled as part of a confirmatory report. Further testing can then be performed on these specimens and the results of the confirmatory testing entered into the record, if desired.

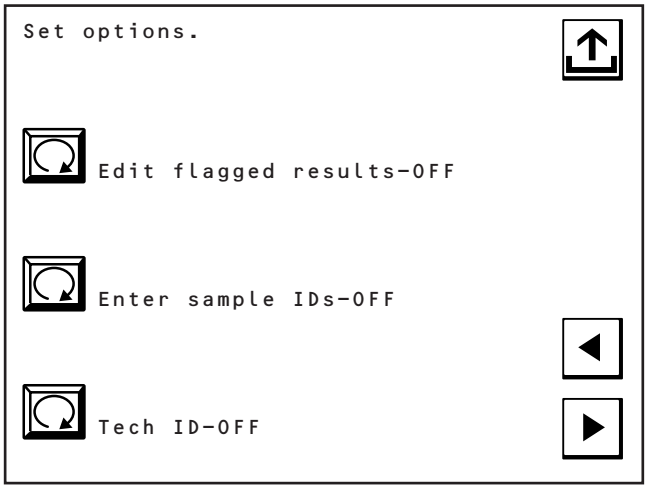
   a. When the action key is touched, the display will show a list of all tests that are to be reported. Touch the selection box next to the tests you want to include in the confirmatory report; a check mark will appear in the box. To remove a selection, touch the box again and the box will become blank.

   b. Touch ◀ when the selections have been made to return to the previous option menu.

3. **Flags for microscopics:**
   As with the confirmatory report, up to five tests can be selected for the microscopics report. This report can be used to list those specimens that may require a microscopic examination. Select the tests for the report in the same manner as for the confirmatory report, then touch ◀ to return to the previous option menu. ("Mark positives" [Step E-2] must be ON in order to obtain the report.)

H. Setup Menu #7

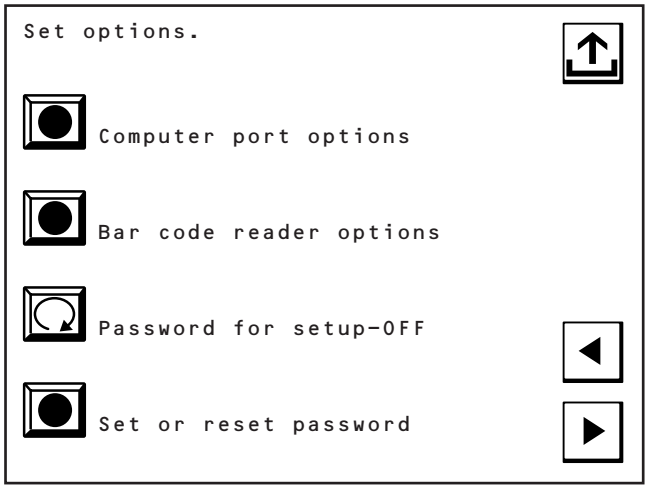
When all options have been selected on the sixth menu, touch ▶ to progress to the next menu in the **Setup** Routine. The menu is displayed as, for example:



1. **Edit flagged results:**
   Results that have been flagged as positive and selected for the confirmatory report can be edited (for example, if confirmatory testing has been performed). Touch the cycle key to turn the option ON or OFF, as desired. This option can be selected only if "Mark Positives" (Step E-2 previously) is ON.
2. **Enter sample IDs:**
   An identification number can be entered for each specimen, either as part of a load list or immediately prior to testing the specimen, if this option is set to ON. Touch the cycle key to turn the option ON or OFF, as desired.
3. **Tech ID:**
   The technician who is performing the testing can be identified on the test results, if desired, by setting this option to ON. The Tech ID can appear on control results only or on both patient and control results. It is shown on the **Ready/Run** screen and is easily changed when necessary (see "Getting Ready to Run," Step 4, in Section 4). Touch the cycle key to select the desired option (OFF; ON, control results only; ON, both patient and control results).

I. Setup Menu #8

When all options have been selected on the seventh menu, touch ▶ to progress to the next **Setup** menu. The menu is displayed as, for example:



1. **Computer port options:**
   If you are sending results to a host computer or LIS (Laboratory Information System), the interface parameters must be specified. Touch the **Computer port options** key to display a new menu.
   a. The first three menu options feature cycle keys to select the correct parameters. The following table shows the possible selections for these options:

Port:	Baud:	Data, Parity:
	1200	8/NONE
ON	2400	7/EVEN
OFF	4800	7/ODD
	9600	7/NONE
	19200	

The port must be ON in order to transfer results to a computer. Refer to the specifications accompanying the computer for information on the required parameters for Baud, Data, and Parity.

NOTE: The computer port can also be turned ON or OFF through the first **Setup** menu, which is unrestricted regardless of whether password protection is being used (see Step I-3 later). If use of the port is changed (from ON to OFF or vice versa) in one menu, the selection is automatically changed in the other menu.

b. The fourth option on the **Computer port options** menu allows selection of the Output Format for the results sent to a computer. A new menu is displayed with the following options and their possible selections:

Output Format:	Checksum:*	Handshake:*
CCS CT200+ CT200	ON OFF	ON OFF

*Not available in CCS format.

The output format you select will depend upon whether you already have a software interface program that allows the transfer of results from either a CLINITEK® 200+ or a CLINITEK® 200 Urine Chemistry Analyzer to a host computer or LIS. When one of these formats is selected ("CT200+" or "CT200"), the data from the CLINITEK 500 instrument will be transmitted in the same format as that sent by the selected instrument *(the printed results, however, do **not** mimic the selected instrument).*

Alternatively, results can be transmitted in the CLINITEK 500 format by selecting "CCS." The parameters for this format are available from your Bayer representative or office.

If either CT200+ or CT200 is selected as the output format, the use of checksum and handshake must also be specified (refer to your computer specification for the requirements). It is also very important that you check the selections made on your CLINITEK 200+ or CLINITEK 200 instrument and enter the parameters identically in the CLINITEK 500 Analyzer (e.g., ID/color/clarity/mark positives ON or OFF). This will help ensure that the data is transferred in the same format as your software program currently is written to accept.

NOTE 1: Two stop bits are always transmitted in the CT200+ and CT200 formats; one stop bit is transmitted in the CCS format.

NOTE 2: If the "CT200" format is selected, results obtained using any of the MULTISTIX PRO Reagent Strips will **not** be sent to the computer. This is because the new tests on the MULTISTIX PRO Strips are not recognized by the CLINITEK 200 Analyzer (and therefore by its corresponding software interface program).

c. Select the correct parameters for all options, then touch ◀ as needed to return to the previous **Setup** menu.

2. **Bar code reader options:**
An optional Handheld Bar Code Reader is available for use with the CLINITEK 500 Analyzer. This reader can be used to scan barcoded identification labels on each specimen cup or tube, rather than entering the specimen ID manually. The Analyzer software must be configured to the appropriate parameters for the barcoded labels being used. Touching the **Bar code reader options** key will change the display to a new menu.

a. **Label:** The Handheld Reader can accept any of four different bar code formats. The format being used can be selected using the **Label** cycle key, or you

can allow the reader to automatically detect the format type. The label options are: Auto detect; Code 39; I-2 of 5 (Interleaved 2 of 5); Codabar; and Code 128.

NOTE 1: Select "Auto detect" only if more than one format is used; faster and more consistent readings will occur if the specific format being used is selected.

NOTE 2: If using Product No. 6469 (the CLINITEK® Bar Code Reader from Hand Held Products, Inc.), the **Label** option will be inactive, with "Auto detect" selected. This Bar Code Reader automatically determines the correct bar code format.

b. **Test bar code:** The bar code label being used should be tested to ensure that the information can be read. After touching the **Test bar code** key, you will be instructed to "Scan bar code label. Verify that information on screen is correct." Scan a label that is representative of the quality and size being used and for which you know the results that should be obtained. The results of the test will be displayed on the screen; compare the displayed result with the known value of the label and use this information to determine if any characters need to be deleted. Return to the previous menu when finished.

NOTE: You may want to test more than one label, especially if they are printed from different sources. If you use more than one format, test at least one label in each format. Refer to Appendix BCR that accompanies the Handheld Reader for complete information.

c. **Leading char. to ignore:** The Handheld Reader can read a bar code that contains up to 30 characters; however, a maximum of 13 characters can be displayed, stored, and transmitted by the Analyzer. All characters in excess of 13 must be ignored (up to a maximum of 18). Characters can be ignored as leading characters (at the beginning of the bar code), trailing characters (at the end), or a combination of both. If you need to ignore any leading characters, touch the cycle key until the desired number is displayed ("0" to "9").

d. **Trailing char. to ignore:** Trailing characters can also be ignored by touching the cycle key until the desired number is displayed ("0" to "9").

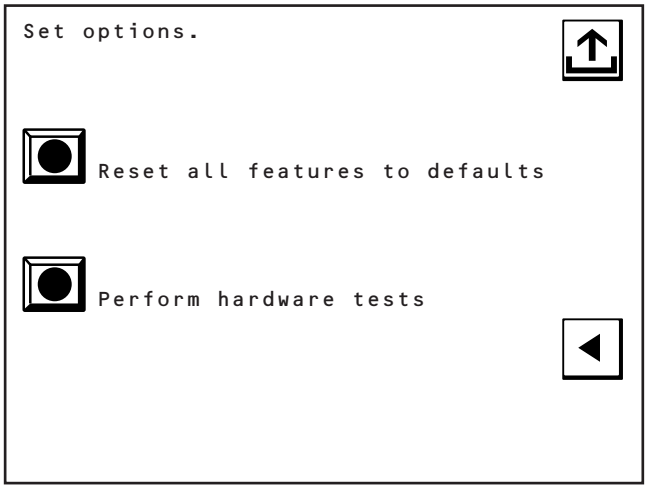
e. When all selections have been made on this menu, touch ◀ to return to the previous menu.

3. **Password for setup:**
You can choose to require entry of a password in order to restrict access to most of the **Setup** Routine option menus by setting this option to ON. The password is requested following the first option menu of the **Setup** Routine, and all further menus are not accessible unless the correct password is entered. If the password option is set to OFF, all option menus in the **Setup** Routine are freely accessible. Touch the cycle key to turn the use of the password ON or OFF.

4. **Set or reset password:**
If the password is being used, you can set a personal password or reset an existing password. The Analyzer also has a default password of "84437," which is *always* active. The personal password can be entered by touching the action key. A numeric keyboard is displayed, from which you can enter up to 6 digits. Touch ↵ when the password has been entered; you will be prompted to re-enter the password for verification. If the same digits are entered the second time, the display will return to the previous menu after displaying the message "New password has been set." If an error is made, you will need to enter the password again and then re-enter the same password for verification.

J. Setup Menu #9

When all options have been selected on the eighth menu, touch ▶ to progress to the final menu in the **Setup** Routine. The menu is displayed as, for example:



1. **Reset all features to defaults:**
   You can return all options in the **Setup** Routine to the manufacturer's default settings through the use of this key. A confirmation screen will be displayed, from which you must touch YES before the options are reset. **All stored results and loadlisted ID numbers will be deleted if the options are reset.**
2. **Perform hardware tests:**
   Several different hardware tests can be performed through this menu option. You may be asked by a Bayer Representative to perform one or more of these tests in order to assist in troubleshooting a problem. When the action key is touched, a new menu of six different options is displayed. The screen also displays the total number of strips that have been read by the Analyzer.
   a. **Strip sensor:** When the action key is touched, the screen displays the prompt "`Place test strip on table.`" If the strip sensor detects the presence of a strip, the message "`Strip detected`" will be displayed.
   b. **Serial port:** This test sends data from the serial port, through a connector, and back into the same port. The data sent and received should be identical.
      i. Obtain a loopback connector, either by making your own or by ordering from Bayer Instrument Service (see Section 9, "Replacement Parts"). The connector is a serial 25-pin male connector on which pins 2 and 3 are connected and pins 4 and 5 are connected.
      ii. Touch the **Serial port** action key to display the test screen. As instructed on the screen, plug the loopback connector into the serial port on the back of the instrument (labeled 10101), then touch ◇ to begin the test. The test will continue until you exit the screen (by touching ◀).
   c. **Touch screen:** This test may be used to determine if the touch screen is functioning properly. When the **Touch screen** key is touched, a screen is displayed that is filled with small boxes. As each box is touched, a check mark (✓) should appear (it disappears when touched again). Touch the center of each box, saving the ◀ key for last.
   d. **Bar code reader:** This test is identical to the **Test bar code** option described in Step I-2-b so you can test your reader without exiting the hardware test screen. If your Handheld Reader is not reading your labels, you should test labels of a known quality to determine whether the problem lies with the labels you are using or with the Handheld Reader itself. The package containing your Handheld Reader includes two sheets of barcoded labels that have been printed to the minimum specifications of the bar code reader. If these labels cannot be read, the problem is probably with your reader. If they read properly, the labels you are using may not be acceptable. Scan the desired label and compare the displayed result with the known value of the label. Return to the previous menu when finished.

e. **Display:** The display can be tested to ensure that all pixels (the lighted elements on the display) are being lit and turned off appropriately. When the **Display** key is touched, the entire screen will be lit for several seconds, then be blank. This series will be repeated twice more before returning to the previous menu. If there are numerous faulty pixels, or if they are located in critical areas, the display may need to be replaced.

f. **Printer:** The internal and/or 80-column external printer can be tested to ensure that all characters are being printed correctly. Ensure that the external printer is turned *on* (if one is being used). Touch the **Printer** key and follow the directions on the screen. Examine the printout for its readability. The display automatically returns to the previous menu.

3. When all tests have been completed, touch ◀ to return to any previous **Setup** menu, or touch ⏏ to return to the **Ready/Run** screen.

When Setup is Complete Touch ⏏ to save!

When you have finished selecting the setup parameters, touch ⏏ to return the display to the **Ready/Run** screen. The changes you made will NOT be saved if you do not touch ⏏.

It is suggested that you print a copy of the setup report to verify your selections and to retain in your files. Touch **Menu** from the **Ready/Run** screen, then touch **Print.** From the Print menu that is displayed, select the option **Setup report.** (If printing from the internal printer, make a photocopy of the report, since the thermal print may fade over time.)

The setup parameters are stored both in the CLINITEK 500 Analyzer and in the program card. If a new program card is installed, you can select to use your current setup configuration from the Analyzer memory. Conversely, if you receive a new CLINITEK 500 Analyzer, but have retained your old program card, you can select to use your current setup configuration from the program card. If both the Analyzer and the program card are new, you can use the printout obtained previously to reselect the desired parameters.

SOFTWARE FLOW CHART

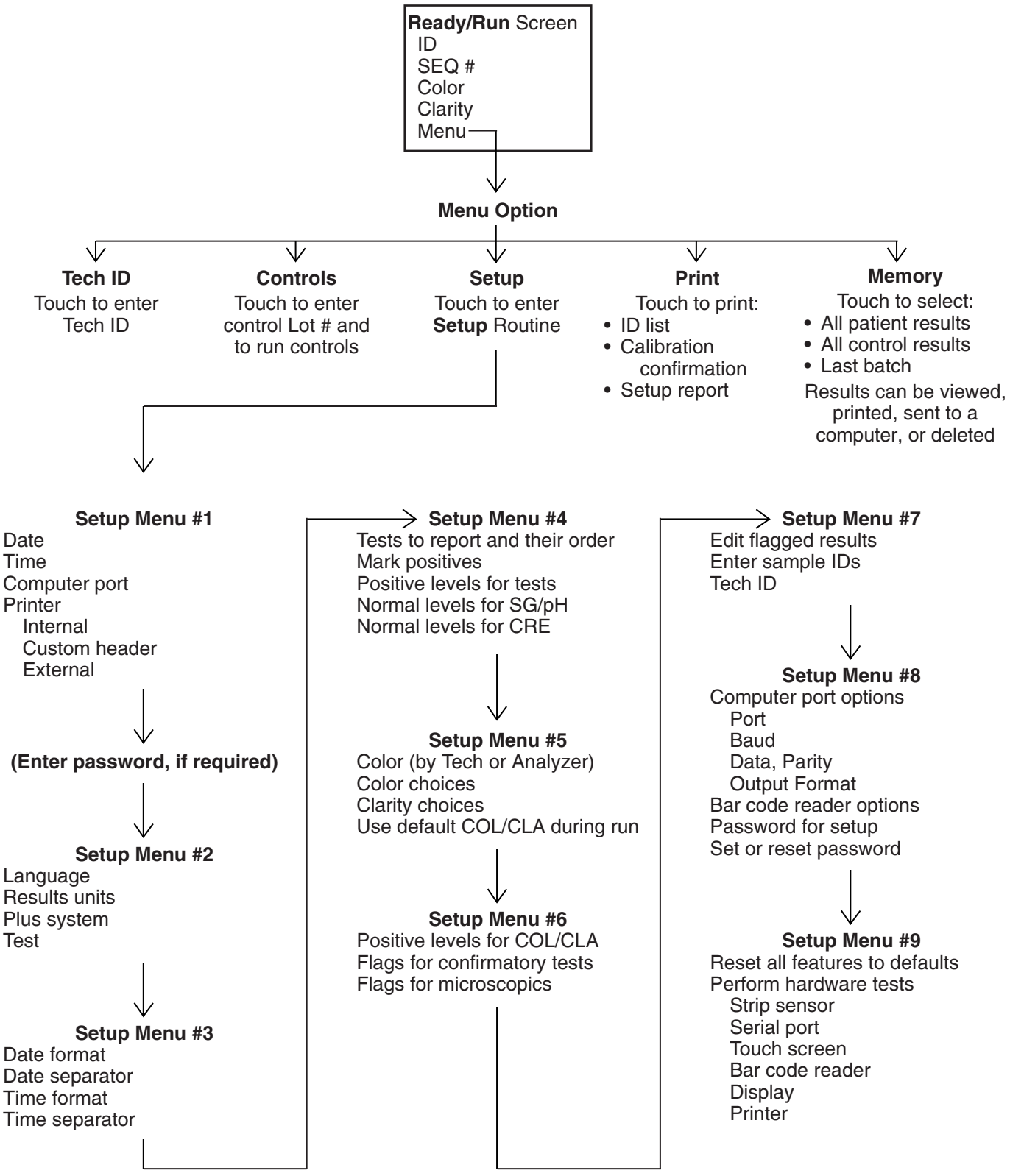


Table 3-1

INSTRUMENT OPERATION

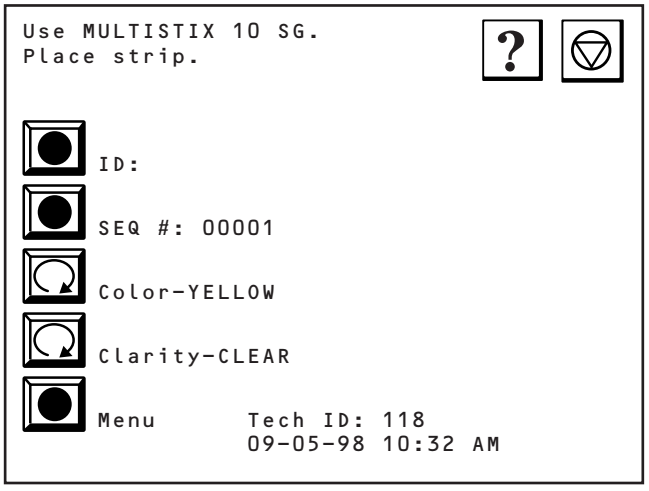
General Information

Following initial installation (Section 2) and selection of your setup options (Section 3), the CLINITEK® 500 Urine Chemistry Analyzer is ready for routine operation. Carefully read this section before beginning any testing.

CAUTION: Do not use anything pointed or hard to make selections on the touch screen. A pencil eraser works well.

Getting Ready to Run

The CLINITEK 500 instrument is designed to be left *on* at all times (except during cleaning procedures). Either the screen saver display or the **Ready/Run** screen (shown below) will be displayed whenever the instrument is not in use. (If the screen saver is being displayed, simply touch the screen anywhere to return to the **Ready/Run** screen.) For example:



If IDs are not being used and color/clarity results are displayed (if being reported), the instrument is ready to use immediately and enters the **Run** mode as soon as a strip is detected on the platform. Whenever the push bar is positioned at the left side of the loading station, the instrument is ready to accept placement of a strip; however, if the bar is positioned to the right, the instrument is not ready and any strip placed on the platform will be ignored.

If you need to access any of the menu items shown on the display, this must be done before a run is started. During a run, most of the key symbols are dimmed, which means the options are not available. The ⊽ key (**Stop Run**) is always available during a run and, depending on the **Setup** options selected, the **Color** and/or **Clarity** keys may be available.

If a key is displayed as a fully lit symbol, that option is available for selection. Touching the specified key symbol causes the following actions:

ID: allows specimen identification numbers to be entered. If ID numbers have been entered into a loadlist, the number of the next specimen in the list is displayed. The number is updated each time a strip is moved to the read area.

SEQ #: allows the sequence number to be changed. The number being displayed represents the sequential number that will be assigned to the next specimen. The number increments each time a strip is moved to the read area.

Color: displays the next option in the series of color selections that can be made for visually determined color results. If color was previously entered through the loadlist, that entry is displayed for the next specimen to be tested; otherwise, either the default description is displayed or the display is blank until the cycle key is touched, depending upon the selection made in Section 3, Step F-4. (If color is determined by the instrument or is not being reported, the display shows "(by Analyzer)" or "(not reported)," respectively.)

Clarity: displays the next option in the series of clarity selections that can be made. Otherwise, the displays are the same as for the **Color** key, except that clarity cannot be determined by the instrument.

Menu: takes you to the Option Menu, from which several additional options can be quickly selected or changed prior to beginning a run.

⊽ (**Stop Run**)**:** cancels the run in progress (available only during the **Run** mode).

? (**Help**)**:** displays additional information about the **Ready/Run** screen.

Before starting each run, perform the following steps:

1. Check that the name of the Reagent Strip being displayed corresponds to the name of the Bayer Reagent Strip for Urinalysis that is to be used for routine urinalysis. **Use of any Reagent Strip other than the one listed will cause erroneous results.** If the names do not agree, select the correct strip name through the **Setup** Routine, as directed in Section 3, Step C-2.

   IMPORTANT: The CLINITEK 500 Analyzer has been optimized for use with Bayer Brand Reagent Strips. The performance characteristics may not be valid for any other brand of strips, the use of which may cause erroneous results. Bayer Corporation does not warrant use of the CLINITEK 500 Analyzer with any reagent strip other than Bayer Brand Reagent Strips.

2. Inspect the strip loading station and push bar for cleanliness and correct positioning. If contaminants are present, remove the push bar, platform, and moving table, and clean as described in Section 5, "Daily Cleaning."

3. The "SEQ #" (sequence number) increments with each strip that is placed onto the instrument. Change the starting number if desired:

   a. Touch the key symbol next to the word **SEQ #.** The display will change to a numeric keyboard, from which the new number can be entered.

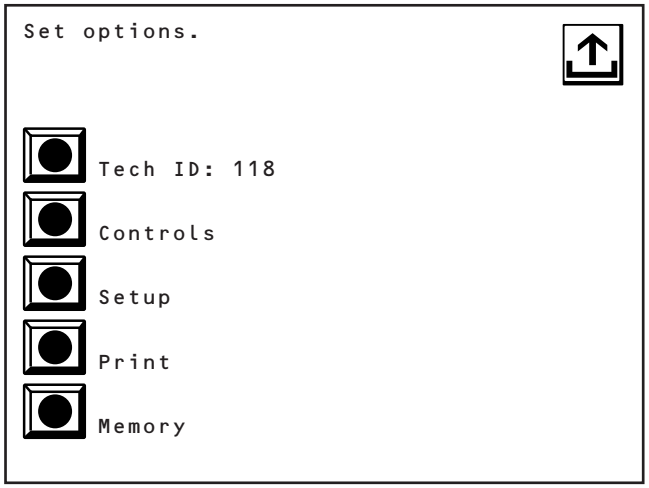
   b. Enter the desired number. The number can be reset to "00001" by touching the special key labeled with that number. If an error is made, or if you only need to change one or two digits, touch the appropriate key (➔ or ➔) to move the cursor to the digit to be changed and enter the correct number.

   c. When the correct number has been entered, touch ↵ to enter the number into memory.

4. Change the "Tech ID" (technician identification) if needed:

   NOTE: If the "Tech ID" key is dimmed, the option can be changed to ON as directed in Section 3, Step H-3.

   a. Touch the **Menu** key symbol to display the Option Menu; for example:



   b. Touch the **Tech ID** key. A numeric keyboard will be displayed.

   c. Enter the identification of up to 13 digits. The keyboard also includes the A-Z key, which allows alphabetic characters to be entered. Touch ↵ from the alphabetic screen to return to the numeric keyboard, then touch ↵ to store the Tech ID and return to the Option Menu screen.

5. If you want to print the ID list (if a loadlist exists in memory), confirmation of the last calibration, or a report of the setup parameters, touch the **Print** key from the Option Menu and select the desired option. Touch ◀ to return to the Option Menu.

6. If you want to run controls before starting the run, touch the **Controls** key from the Option Menu and proceed as directed next.

Testing Controls

Negative and positive controls should be run on a regular basis to provide a check on the performance of the Bayer Reagent Strips and on the instrument operation. Testing controls provides confidence that the Reagent Strips are reacting and being read properly. Errors resulting from user techniques can also be detected. It is suggested that controls be run under the following conditions:

- At the start of the day's run;
- When using a new bottle of Reagent Strips;
- Whenever test results are in doubt;
- When training new instrument operators.

CHEK-STIX® Positive and Negative Control Strips for Urinalysis are available for use on the CLINITEK 500 Analyzer. The solutions prepared using the Control Strips provide positive, negative, or defined reactions when used with traditional Bayer Reagent Strips for Urinalysis. Alternatively, a urine specimen from a normal, healthy individual can be used as a negative specimen. Additional information on CHEK-STIX Positive and Negative Control Strips can be found in Section 6 of this manual and in the package insert for the Control Strips.

NOTE: If using MULTISTIX PRO® Reagent Strips, quality control should be performed using commercially available controls that include values for each test on the strip; CHEK-STIX Control Strips are not suitable for use with these products. For information about control manufacturers, contact your Bayer office or representative. In the United States, call the Bayer Technical Care Center at 1-877-229-3711.

To test control specimens, proceed as follows:

1. Prepare the appropriate control solution(s) by following the directions found in the package insert or on the bottle label.
2. Touch the **Menu** key symbol from the **Ready/Run** screen, then touch the **Controls** key (if not already done). The display will change to a numeric keyboard, from which the lot identification of the controls can be entered, the sequential number reset, and the control run started.
   a. Notice the control sequential number displayed immediately to the left of the lot number (e.g., "C0035"). If you want to reset this number, touch the key labeled **C0001.**
   b. Enter the lot identification of the first control to be tested. If alphabetic characters are needed, touch the **A-Z** key to display the alphabetic keyboard. Touch ↵ after entering the letters to return to the numeric display.
   c. Touch ↵ when you are ready to test the control.
3. The display will prompt "Place strip." Completely immerse all reagent areas of the Bayer Reagent Strip in the control solution. Immediately remove the Reagent Strip. While removing, slowly run the edge of the entire length of the Reagent Strip against the side of the container to remove excess control solution.
4. Place the reagent strip, with reagent areas up, onto the strip supports of the strip loading station, to the right of the small embossed arrow (▽) and against the rear wall of the platform (Figure 4-1).

Figure 4-1

NOTE: Be sure the Reagent Strip is lying parallel to the push bar. The end of the strip should be **against the rear wall of the platform** and should not be touching the bottom of the strip loading station. Improper placement may cause the instrument to jam or the strip to be incorrectly aligned under the readheads.

5. Repeat Steps 2-b through 4 for each additional control.
6. The strip(s) will automatically be advanced along the strip loading station, under the readheads for reading, then into the waste bin. The results will then be printed (unless all printers have been turned OFF through the **Setup** Routine) and stored in memory. If the computer port is ON and CCS is selected as the output format (see Section 3, Step I-1), the control results will also be transmitted to the host computer.
7. After all controls have been run, press ⏏ (after the symbol is displayed again) to exit the control screen.
8. The control solution should produce the values stated in the product's package insert. If the control results fall outside of these values, the following sources of error may have occurred:
   a. Improper technique or instrument setup. Check that the Reagent Strip being used corresponds to the Reagent Strip name given on the **Ready/Run** screen. Carefully repeat the control procedure as described above.
   b. Deterioration of the Reagent Strip test areas due to exposure to light, ambient moisture or heat. Obtain a fresh bottle of the Bayer Reagent Strips being used and repeat the control procedure. If fresh Reagent Strips fail to give results within the expected values, proceed to Step c.
   c. Deterioration of the control solution. Prepare a fresh control solution and repeat the control procedure. If fresh solution fails to give results within the expected values, proceed to Step d.
   d. Deterioration of the control product. Obtain a fresh bottle of control product and prepare a fresh control solution, then repeat the control procedure. If the fresh control solution fails to give results within the expected values, proceed to Step e.
   e. CLINITEK 500 instrument malfunction. Perform an Initial Instrument Check procedure (see Section 2). If the Initial Instrument Check or the control procedure cannot be successfully completed and an instrument malfunction or reagent strip problem is suspected, see Section 8, TROUBLESHOOTING AND SERVICE, or contact the Customer Service Department for assistance.

Testing Routine Specimens

A. Basic Operation

The steps described in this section are the same regardless of whether you are running with or without the use of ID numbers. Read this section completely to understand how the instrument operates during the **Run** Mode.

1. If clarity is being reported and/or color being entered by the technician, select the color and/or clarity description for each specimen. Touch the cycle key(s) as needed until the appropriate description is being displayed. (Alternatively, enter the color and clarity by scanning the appropriate barcoded symbols provided with the Handheld Bar Code Reader.) This should be done before continuing to the next step; however, you can change the description up to the point at which the strip is moved.

2. Completely immerse all reagent areas of a Bayer Reagent Strip in *fresh,* well-mixed, uncentrifuged urine. Immediately remove the Reagent Strip. While removing, slowly run the edge of the entire length of the Reagent Strip against the side of the urine container to remove excess urine. **Do *not* blot the edge of the strip against a paper towel.**

   NOTE: The instrument performance has been optimized for use with unblotted strips, and results may differ if the strips are blotted.

3. Place the Reagent Strip, **with reagent areas facing up,** onto the strip supports of the strip loading station, to the right of the small embossed arrow (▽) and against the rear wall of the platform (Figure 4-2).

Figure 4-2

NOTE: Be sure the Reagent Strip is lying parallel to the push bar. The end of the strip should be **against the rear wall of the platform** and should not be touching the bottom of the strip loading station. Improper placement may cause the instrument to jam or the strip to be incorrectly aligned under the readheads.

4. The presence of the Reagent Strip is detected as soon as it is placed on the loading station. If the instrument was previously at the **Ready/Run** screen, detection of the first strip immediately activates the timing and movement functions. The push bar moves the strip along the loading station to the read area and the SEQ # increments. The strip is moved along the platform by a series of pins that move every seven seconds, passing under each of the two readheads for analysis and then into the waste bin.

   NOTE: If the instrument is already in the **Run** Mode, there may be a delay of up to seven seconds after the strip is placed on the loading station before the push bar moves. The amount of delay depends on the status of the timing cycle for the strips currently being analyzed.

5. For each new specimen to be tested:

   a. Enter the color and/or clarity description.

   b. Dip and place the Reagent Strip for the specimen just entered.

   The instrument continues to move the strips across the read area until the final strip is moved to the waste bin. A new strip can be placed on the loading station at any time prior to then.

   NOTE: You will have very little time to enter the color/clarity after placing the strip. Therefore, it is strongly suggested that you enter the color and clarity of each specimen *before* dipping the Reagent Strip.

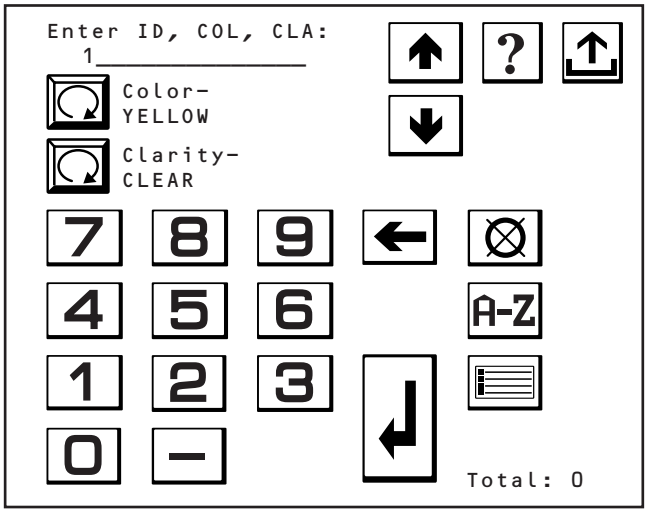
6. See Part D later in this section for information on printing and/or transmitting the results.

7. **Cancelling a run:** If a problem occurs that requires the run to be stopped before completion of all readings, touch the ⊽ key symbol (**Stop Run**) in the upper right corner. You will be given the option of cancelling the entire run or cancelling only the last strip that was placed on the platform. If the entire run is cancelled, all strips on the platform will be moved immediately to the waste bin. No results will be reported (and no SEQ # assigned) for any strip that had not been read at both readheads prior to pressing ⊽; the specimens for those strips must be retested. If only the last strip is cancelled, the run will continue and a new strip can be tested, using the same SEQ #.

B. If IDs are Used in a Loadlist:

Up to 100 specimen IDs can be entered as a loadlist before starting the run, as described below.

1. Touch the **ID** key from the **Ready/Run** screen to enter the number for the first specimen. The ID entry screen is displayed as, for example:



   The ID number can be entered using the numeric keyboard. If color is being entered by the technician and/or clarity is being reported, these must be entered at the same time. They can then be edited while running the specimens, immediately prior to dipping each Reagent Strip.

2. Enter the ID for the first specimen. If alphabetic characters are needed, touch the A-Z key to display the alphabetic keyboard (touch ↵ to return to the numeric keyboard). Alternatively, scan the ID number from a barcoded label using the Handheld Bar Code Reader.

   NOTE: Do NOT touch or scan ↵ from the ID entry screen until *after* the color and clarity have been entered.

3. Enter the color and clarity descriptions, if desired, by touching the **Color** and/or **Clarity** key symbols as needed to display the correct description. If "Use default COL/CLA during run" was set to ON, the default values of "YELLOW" and "CLEAR" will be displayed; if it was set to OFF, the descriptions for both will be blank until the key is touched. Alternatively, scan the appropriate color and clarity bar codes, using the Handheld Reader and the special color/clarity bar code card provided with the Reader.

4. Touch ↵ (or scan the ↵ code from the color/clarity card) to enter the number, color, and clarity into memory. (A warning tone will sound if an entry is missing.) The number to the left of the ID will increment to indicate the loadlist order of the next ID to be entered; the number in the lower right corner of the display will also increment to show the total number of IDs in the loadlist.

   NOTE: There is no need to scan the ↵ bar code if you are scanning barcoded ID numbers **AND** if:
   - neither color nor clarity is being used
     or
   - clarity is not being used and color is being determined by the Analyzer.

5. Repeat Steps 2 to 4 above for each specimen.

   NOTE: Duplicate ID numbers ARE allowed by the system.

6. To **review, change,** or **delete** a loadlisted number or color/clarity description that has already been entered, use the ↑ and ↓ keys to display the desired number, using the loadlist order number to help you locate the proper location:

   NOTE: The ID number cannot be changed or deleted during the **Run** mode; changes must be made through this screen while the instrument is in the **Ready** mode.

   a. Change the ID number using the ← key to move the cursor to the left as needed, then enter the correct number.

   b. Delete the number from the loadlist by touching ⊗; you will be given the option to delete only the ID number being displayed or all IDs in memory. Touch the desired option.

   c. Edit the color and/or clarity description as described in Step 3 above.

   d. Touch or scan ↵ to accept the new number and color/clarity descriptions.

7. When all IDs have been entered into the loadlist, you can print the list by touching ☰. Then touch ⏏ to return to the **Ready/Run** screen to begin testing specimens. (The ID list can also be printed by touching **Menu** from the **Ready/Run** screen, then touching **Print** and selecting **ID list.**)

   NOTE: Once testing is started, no additional IDs can be added to the loadlist, nor can an ID number be changed or deleted until the run is completed or cancelled. If the run is cancelled, the remaining IDs in the loadlist can be edited, but no new IDs can be added until the run is complete.

8. Test each specimen in the same manner as described in Step A previously ("Basic Operation"). The **Ready/Run** screen will show each ID number and the color/clarity descriptions in the same order as they were entered into the loadlist. For each specimen:

   a. Check that the ID number and color/clarity descriptions are correct for the specimen about to be tested. Edit the color and clarity, if necessary, as described in Step A-1.

   b. Dip and place a Reagent Strip as described in Steps A-2 and A-3.

9. When the strip for the last loadlisted specimen has been moved to the read area, you will not be allowed to place any additional strips on the table. The push bar will stay at the right side and the display will change to "`Completing Run. Please Wait.`"

C. If IDs are Used Without a Loadlist

Specimen IDs can also be entered immediately prior to testing each specimen, as follows:

1. Touch the **ID** key to enter the number for the first specimen. The ID entry screen is displayed (see Step B-1 above).

2. Enter or scan the ID number for the specimen about to be tested; if needed, enter or scan the color and clarity descriptions (see Steps B-2 and B-3 for complete directions). When this information has been correctly entered, touch ↵ (or scan the ↵ code from the color/clarity card).

   NOTE: There is no need to scan the ↵ bar code if you are scanning barcoded ID numbers **AND** if:
   - neither color nor clarity is being used
     or
   - clarity is not being used and color is being determined by the Analyzer.

3. The display will change to allow entry of the next ID number, and the push bar will move to the left so a strip can be placed on the loading station. Dip and place a Reagent Strip, as instructed in Steps A-2 and A-3.

   NOTE: If another ID is entered without a strip being detected, the instrument automatically creates a loadlist (see Step B previously).

4. When a Reagent Strip is detected at the loading station after a single ID number has been entered, two changes occur on the display:
   - The number to the left of the ID changes to the sequence number of the specimen being tested. This number will increment each time a strip is moved to the read area.
   - The prompt at the top of the display changes each time ↵ is pressed (after entering the ID and color/clarity of a specimen) to the prompt "`Place strip.`" After a strip is moved to the read area, the prompt returns to "`Enter ID, COL, CLA.`"
5. **For each specimen:**
   a. Enter the ID number, color, and clarity.
   b. Touch or scan ↵.
   c. Dip and place the Reagent Strip for the specimen just entered.

   NOTE: The display remains at the ID Entry screen throughout the entire run when IDs are entered immediately prior to testing the specimen.

D. Printing and Transmitting Results

Results are transmitted to the printer and/or computer as soon as all reagent areas on the strip have been read. However, if a record is flagged for the confirmatory report and "Edit flagged results" is ON (see "End-of-Run Reports" next), that record is not transmitted until after the end-of-run reports have been exited.

End-of-Run Reports

If you marked any analytes to be flagged for confirmatory and/or microscopic tests and if "Mark positives" is ON (in the **Setup** Routine), one or two end-of-run reports may be displayed when the run is completed. The Confirmatory and/or Microscopic Report screens will show the SEQ # and ID of the record, plus the abbreviation for each analyte that was positive and marked for flagging. Up to five records may be displayed on one screen; additional records can be viewed by touching the ↑ and ↓ keys. If there are records in both the Confirmatory and Microscopic Reports, the Confirmatory Report will be displayed first. *If results are to be edited, this must be done before exiting the Confirmatory Report* (see "Editing Results" next). You can print a report by touching ☰. Then touch ⏏ when you are ready to exit the report screen.

NOTE: A third report will be displayed if there are any records for which an error was reported for one or more analytes. This report will be displayed last, and any specimens listed should be retested.

Editing Results in the Confirmatory Report

If you perform confirmatory testing on any of the specimens and want to edit the reported results, this is done from the Confirmatory Report screen. **You must first have specified one or more tests for the Confirmatory Report and have selected ON for the "Edit flagged results" option** in the **Setup** Routine (Section 3, Steps G-2 and H-1).

1. While the Confirmatory Report is being displayed, use the ↑ and ↓ keys to move the highlighting to the desired record, then touch ↵ to select the record.

2. The results obtained for the flagged (positive) tests will be displayed. Touch the cycle key next to the test name to change the displayed result to the next option of the available reported results. Once the cycle key is touched, the result for that test will be printed and stored with an exclamation point (!), *even if the result is reset to its original value.* If the selected output format is "CCS" (see Section 3, Step I-1b), the "!" will be transmitted with the results. Touch ◀ when editing is complete for that record to return to the Confirmatory Report.
3. Repeat Steps 1 and 2 above for each desired record. When all editing is complete, touch ⮥ to exit the Confirmatory Report. *Once you leave the Edit routine, you will not be able to edit the run any further.*
4. If there are records in the Microscopic Report, they will be displayed next. After both the Confirmatory and Microscopic Report screens have been exited, results for the records included in the Confirmatory Report are sent to the printer and/or computer (all other records are printed/ transmitted as soon as they are available).

Recalling Results

Up to 500 patient records and 200 control records are stored in memory. If you want to recall one or more records, proceed as follows:

1. Touch **Menu** to display the Option Menu, then touch **Memory.**
2. You can choose to recall all patient records, all control records, or the last batch of patient records. The number of records in memory is shown next to the first two options. Touch the desired option.
3. The first (earliest) record of the selected group will be displayed. The date and time the record was stored is shown, along with the technician ID (if available), SEQ #, and ID for the record. All results are then listed; positive results (as defined through the **Setup** Routine) are flagged with an asterisk (*) and edited results with an exclamation (!).
4. Locate the first record you want to review using the movement keys shown on the display. The next lower- or higher-numbered record in memory is recalled when the 🡅 and 🡇 keys are used; the record 10 lower or higher is recalled when the 🡅10 and 🡇10 keys are used.
5. **Printing records from memory:** If you want to print one or more records, touch ☰; you will be given several printing options:
   a. **Print only this result:** The record that was displayed when the ☰ key was touched can be printed. The SEQ # and ID of that record will continue to be displayed on the print option menu.
   b. **Print a group of results:** You can specify the beginning and ending records to be printed; all records in the sequential group will be printed. Use the movement keys to display the first record (lowest SEQ #) you want to have printed, then touch ↵ to change the selection to the last record to be printed. This record must have a SEQ # that is higher than or the same as the first record. Touch ↵ to begin printing.
   c. **Print all patient (control) results:** All records that were recalled can be printed when this option is selected.

   After printing is complete, the screen returns to the first (earliest) record of the group selected in Step 2 previously. (If "Print a group of results" was selected, the display first returns to the screen from which the group was selected. Touch ◀ as needed to return to the first record.)

6. **Resending records from memory:** If you want to resend one or more records to a host computer or LIS, touch ⊖; you will be given the same options as given previously for printing records from memory:
   - Send only this result
   - Send a group of results
   - Send all patient (control) results

   Select the records to be resent in the same manner as in Step 5 above.
7. **Deleting results from memory:** If you want to delete all patient or control results from memory, touch the ⊗ key. You will then be asked to confirm the deletion.
8. When done, touch ◀ to return to the previous menu or touch ⏏ to return to the **Ready/Run** screen.

Operating Notes

- **When printing with a Form Printer:** Each set of results is stored in memory until a form is inserted into the Form Printer. When a form is detected as being in place, the next set of results is sent to the printer. Check each form immediately after it is printed to ensure that all results have been printed and are clearly readable. If there is a problem with the printed form, immediately reprint the last report as follows:

  NOTE: If using the CLINITEK® Form Printer, use the "Reprint" key on the Form Printer, rather than touching the **Reprint last result** key on the instrument display.

  a. Touch the selection key next to **Reprint last result** that is displayed on the same screen as the message "`Printing-Please wait.`" As long as the ✓ appears in the selection key, the last set of results will be reprinted each time a form is inserted into the printer.
  b. Insert a new form into the Form Printer. (A form must NOT be inserted before touching **Reprint last result** or the last set of results will be lost.)
  c. When the report has been printed correctly, touch the selection key again to remove the ✓. The next set of results will be printed when a form is inserted.
- **If a strip should become jammed** under the readhead to the extent that movement of the strips is prevented, touch ▽ to stop the run and return to the **Ready/Run** screen. Record the information provided on the Results Error Report to determine the specimen(s) that must be retested. Then turn the instrument *off* and remove the fixed platform (see Section 5, "Daily Cleaning," Step 4). Remove the jammed strip, reinstall the platform, and turn the instrument *on.* Retest the specimen(s) for which there were no results.
- **Calibration confirmation:** A report of the most recent successful calibration can be printed if desired. Touch **Menu** from the **Ready/Run** screen, then touch **Print** and select **Calibration confirmation.** The date and time of the latest successful calibration will be printed.
- **Thermal print (from the internal printer) will fade** with time, especially when exposed to light. The print will also fade if covered with transparent tape or when exposed to extremes in temperature or humidity.
- **The instrument does not detect when the internal printer is out of paper** and therefore will continue printing results even if there is no paper. However, the last several feet of paper on the roll contain a pink edge; the roll should be changed when this appears. Any records for which you do not have printed results can be reprinted by recalling the last batch of records, then printing the appropriate records.
- **Empty the waste bin** as it starts to fill to prevent problems with strips jamming as they leave the read station.

CARE OF THE INSTRUMENT

General Cleaning

Keep the exterior of the CLINITEK® 500 instrument free of dust at all times. If needed, the exterior may be cleaned using a *damp* cloth and a mild detergent. Do not use any type of solvent, oil, grease, silicone spray, or lubrication on any part of the instrument.

Daily Cleaning

The fixed platform, moving table, reagent strip hold-down plate, push bar, and liner should all be cleaned at least once each day or after running 300 strips, whichever is more frequent. If the display screen is used to enter ID, color, or clarity during the run, it should be cleaned once each day also, as directed in the following steps.

1. With the instrument at the **Ready/Run** screen (and the run completed), turn the Analyzer *off.*

   NOTE: If the instrument is turned *off* from any screen other than **Ready/Run** (and with the run completed), the moving table may not be in its lowest position and you will be unable to reinstall the platform. See "General Information" in Section 8 for further information.

2. Remove the push bar by tilting it slightly upwards and pulling straight out (Figure 5-1).

Figure 5-1

3. Remove the waste bin liner (if being used) and discard the used Reagent Strips into an appropriate container, according to your standard laboratory procedures.
4. Remove the fixed platform by pulling the entire assembly towards you (Figure 5-2).

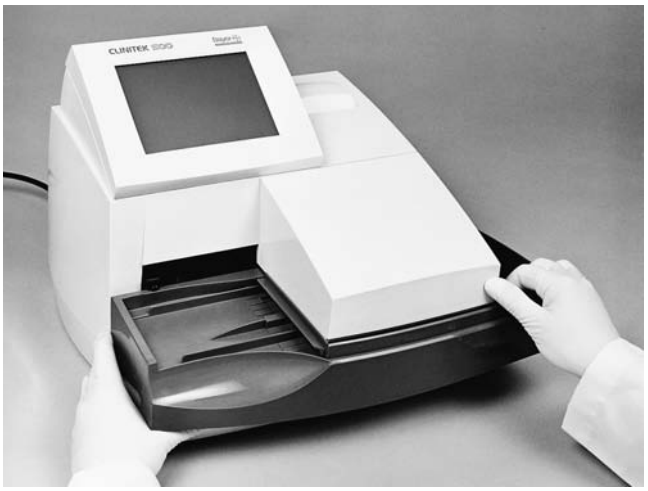


Figure 5-2

5. Remove the moving table in the same manner (Figure 5-3).

Figure 5-3

6. Remove the holddown plate from the fixed platform by pressing up against the tab at the back of the plate (Figure 5-4). Then pull the other end from its retaining hole. **Removal of the holddown is important for proper cleaning.**

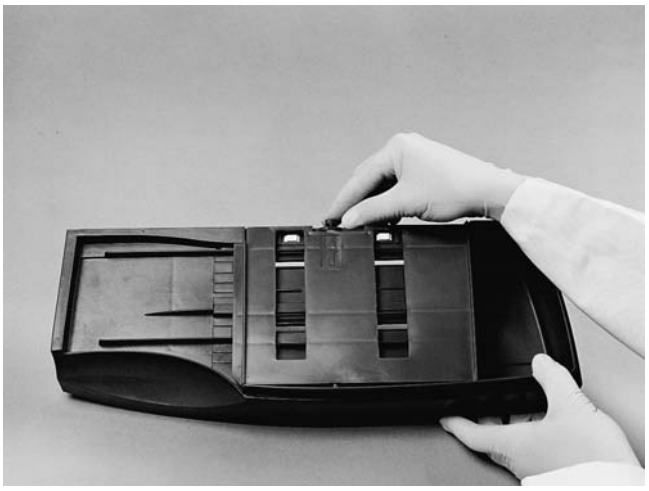


Figure 5-4

7. Clean each piece (push bar, platform, holddown, table and liner) with warm water and mild soap. **Do not use any type of solvent.** When cleaning the platform, avoid wiping across the two white calibration bars; use a cotton-tipped swab, wetted with plain water, to clean the bars.

   NOTE: If the holddown and/or push bar are extremely dirty, they may need to be soaked in order to loosen the dried residue. An extra moving table, holddown, and push bar are supplied with your instrument so you can reassemble your instrument while the original pieces are soaking. The liner is disposable and may need to be replaced periodically.

8. Rinse each piece thoroughly and dry with a paper towel or soft cloth. Allow the calibration bars on the platform to air dry.

   NOTE: After cleaning, inspect the calibration bars for scratches, marks, or discoloration. If the bars cannot be cleaned, the platform must be replaced (see Section 9, "Replacement Parts").

9. If you want to disinfect the parts, do that now, as instructed in "Disinfection," found later in this section.

10. Reinstall the moving table as follows:

    a. Hold the table with the small rectangular tab facing to the back.

    b. Align the two grooves on the bottom of the table with the edges of the platform on which the table rests.

    c. Gently push the table in as far as it will go. It must be pushed past a detent in order to be correctly in position.

11. Reinstall the holddown and fixed platform:

    a. Position the holddown with the arrow side facing up and the arrow pointing to the back. Place the pin on the front of the holddown into the hole at the front of the fixed platform. Then align the tab at the back of the holddown with the slot at the back of the platform and snap the holddown into place. Make sure the white calibration bars are visible.

b. Align the two grooves on the bottom of the fixed platform with the arms extending from the instrument. (The ledges on the sides of the holddown align just outside the read area cover, and the top edge of the platform aligns just under the cover.) Gently push the platform in as far as it will go. (It must be pushed past a slight detent to be correctly positioned.)

   CAUTION: If the platform does not push in with only gentle pressure, do not force it! Ensure that the moving table is correctly positioned and attempt to reinstall the platform.

12. Hold the push bar by its flattened end and, with this end slightly upward, insert the peg on the other end of the bar into the hole in the pusher mechanism. Lower the push bar into place.
13. Place the clean (or a new) liner into the waste bin.
14. Clean the display screen, when needed, with a soft, nonabrasive cloth that has been dampened with a mild glass cleaner (do not use bleach). Do not spray the glass cleaner directly onto the screen. Do not use laboratory wipes, such as Kimwipes®, since they may scratch the sceen.
15. Turn the instrument power *on.*

Disinfection

To disinfect the push bar, holddown, platform, table and display screen, perform the following steps. This procedure can also be used when taking the instrument out of service.

IMPORTANT: Refer to the labeling accompanying the disinfection products for complete instructions on their use.

1. Remove, clean, and dry the push bar, fixed platform, holddown, and moving table as directed in "Daily Cleaning," Steps 1 to 7. (The liner should not be disinfected. When it becomes contaminated or develops any cracks, discard it into an appropriate container and use a new liner.)
2. Several solutions are safe to use on the pieces when they are used for no longer than 10 minutes once a day. Prepare one of the following solutions:
   - **Household Bleach** (5% sodium hypochlorite)—can be used either full strength or diluted to as much as a 1:20 dilution. To make a 1:20 dilution, add 5 mL of bleach to a container and add 95 mL of water, for a total volume of 100 mL. (To make a 1:10 dilution, combine 10 mL of bleach and 90 mL of water.)

     NOTE: Bleach CANNOT be used on the display screen.
   - **Cidex®*** and **Theracide®***—these products (or their equivalent) can be purchased for use in general disinfection. Prepare and use the solution according to the directions that come with the product.

   CAUTION: Do NOT use isopropyl alcohol or any product containing phenol (such as Amphyl®*), as these will cause damage to the calibration bars.
3. Completely immerse the pieces in the solution for **no longer than 10 minutes.** Rinse each piece thoroughly with clear water.
4. Dry each piece with a paper towel or soft cloth, using care when drying around the pins on the moving table. Allow the white calibration bars on the platform to air dry.
5. Reinstall the pieces as directed in "Daily Cleaning," Steps 10 to 13.

*__Cidex__ (registered trademark of Johnson & Johnson) is a 3.2% glutaraldehyde solution.
__Theracide__ (registered trademark of Lafayette Pharmaceuticals, Inc., Lafayette, IN) is a quaternary ammonium solution.
__Amphyl__ (registered trademark of National Laboratories, L&F Products, Montvale, NJ) is a phenol solution.

6. Disinfect the display screen, if needed, using either Cidex or Theracide solution (or their equivalent) only; **do NOT use bleach.** Wipe the solution on the screen using a soft, nonabrasive cloth and allow to remain for 10 minutes. Do NOT spray or pour the disinfectant directly onto the screen. Rinse using a clean, soft cloth dampened with water, then dry.

NOTE: Repeated or prolonged soaks over a long period of time with glutaraldehyde solutions may cause a slight fading or discoloration of the platform and table, and a cloudy appearance to the push bar; however, these changes will not affect performance.

Changing the Paper

1. Be sure the instrument is at the **Ready/Run** screen.
2. Notice the large tab on the back side of the instrument that secures the cover in place (Figure 5-5). Press in firmly on the bottom edge of the tab and lift the cover off.

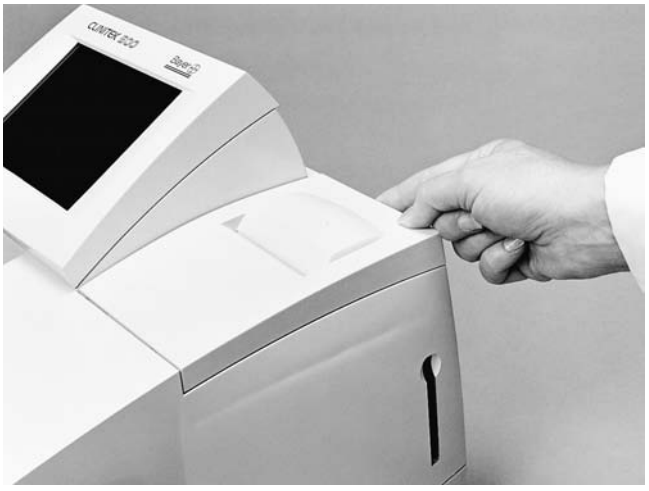


Figure 5-5

3. If there is paper remaining on the roll, lift up the roll and tear the paper between the roll and the printer. Then gently pull the paper through the printer in its normal direction of travel or rotate the wheel on the right side to advance the paper. Otherwise, remove the empty core.
4. Obtain a new roll of paper (Product No. 5773); unroll several inches and trim the end into a long "V". Hold the roll just above the printer, with the paper unrolling from underneath. Feed the end of the paper under the roller, then rotate the paper advance wheel in a clockwise direction (toward the back) until several inches of paper are exposed above the printer (Figure 5-6).

Figure 5-6

5. Set the paper into position behind the printer. Then, place the front tabs of the cover into their slots and feed the end of the paper through the opening in the cover. Snap the cover into place.

SUPPLIES & OPTIONAL EQUIPMENT

Bayer Reagent Strips for Urinalysis (e.g. MULTISTIX® 10 SG)

Many different configurations of Bayer Reagent Strips can be used on the CLINITEK® 500 Analyzer. Contact your Bayer office or representative for the configurations available in your country.

CHEK-STIX® Positive and Negative Control Strips for Urinalysis

Combo Pak (Product Number 1364 — U.S.A. and Canada)
(Product Number 1364E—all other countries)
Positive Control Strips (Product Number 1360)

CHEK-STIX® Positive and Negative Control Strips for Urinalysis (Figure 6-1) provide a performance check for the CLINITEK 500 Instrument/Reagent Strip System. CHEK-STIX Control Strips provide confidence that the Reagent Strips are reacting and being read properly. Errors resulting from user technique can also be detected.

Figure 6-1

CHEK-STIX Control Strips are reconstituted in distilled water to make up a CHEK-STIX control solution. Instructions are included in the package insert and on the bottle label, and test results that should be obtained are listed in the package insert.

NOTE: CHEK-STIX Control Strips are not suitable for use with MULTISTIX PRO® Reagent Strips.

The Control Strips are available as a Combo Pak, which contains one bottle each of the Positive Control Strips and Negative Control Strips (25 strips/bottle). The Positive Control Strips are also available as a separate product (one bottle of 25 strips).

CLINITEK® Handheld Bar Code Reader (Product Number 6469)

The CLINITEK® Handheld Bar Code Reader (Figure 6-2) can be connected to the RJ45 interface port on the CLINITEK 500 instrument. The Handheld Reader can be used to enter the identification numbers from barcoded labels, rather than manually entering each number before the specimen is tested. Color and clarity can also be scanned from special bar codes that are included with the Handheld Reader.

Figure 6-2

CLINITEK® 500 Waste Bin Liners

(Product Number 6472)

The CLINITEK® 500 Waste Bin Liners are reusable plastic liners that fit into the waste bin of the CLINITEK 500 instrument. They provide a safe, convenient method for removal of used Reagent Strips. Each package contains 5 liners.

STAR Form Printer

(Product Number 5257)

The STAR Form Printer (Figure 6-3) is available from Bayer for use with the CLINITEK 500 instrument. It can be interfaced to the instrument and all results then printed onto multi-copy forms. Three-copy forms (Product Number 5163A) and replacement ribbon cassettes (Product Number RC200P) are available from Bayer for use with the printer.

Figure 6-3

MINOR REPAIR

General Information

The CLINITEK® 500 Urine Chemistry Analyzer is a self-contained instrument that requires very little maintenance. With proper care and use, the instrument should operate reliably with a minimum of operator attention. The only minor repair that can be performed is the replacement of the printer, should this ever become necessary. In addition, the touch screen can be recalibrated, if needed. This section is provided as an aid in performing these procedures; for any other repairs, refer to Section 8, TROUBLESHOOTING AND SERVICE, for instructions on obtaining service for your instrument.

Printer Replacement

Tools Required:
None
Parts Required:
Printer (Part No. 40451012)

Procedure:

1. **WARNING: TURN THE INSTRUMENT *OFF* AND REMOVE THE AC ELECTRICAL CORD FROM THE OUTLET.**
2. Remove the cover on the internal printer by pressing in on the lever on the back of the printer cover and lifting up on the cover (Figure 7-1).

Figure 7-1

3. Remove the roll of paper from the printer by tearing the paper between the roll and the printer, then gently pull the paper through the printer in its normal direction of travel or rotate the wheel on the right side to advance the paper.
4. **To remove the printer:**
   a. Carefully remove the clear plastic shield that is adhered to the front of the printer. Be careful not to tear the adhesive pads.
   b. The printer hooks under a ledge at the front and snaps into position at the rear with a small lever (Figure 7-2). Press out on the lever and lift up on the printer. Raise the module out of its cavity by lifting up and back.

Figure 7-2

c. The printer is connected to the instrument through a flat 14-pin interface cable (Figure 7-3) for transfer of data (1). The cable slides into a connector (2) that snaps down to secure the cable into position.

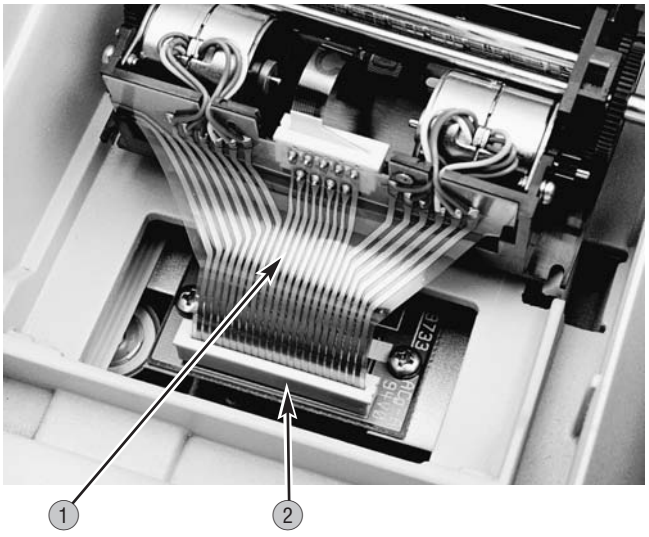


Figure 7-3

Unsnap the connector by lifting up on both sides of the top plate; it will raise by about 1/16" (2 mm). Then gently pull the interface cable from the connector (Figure 7-4). (You may need to wiggle the cable slightly to loosen it initially.)

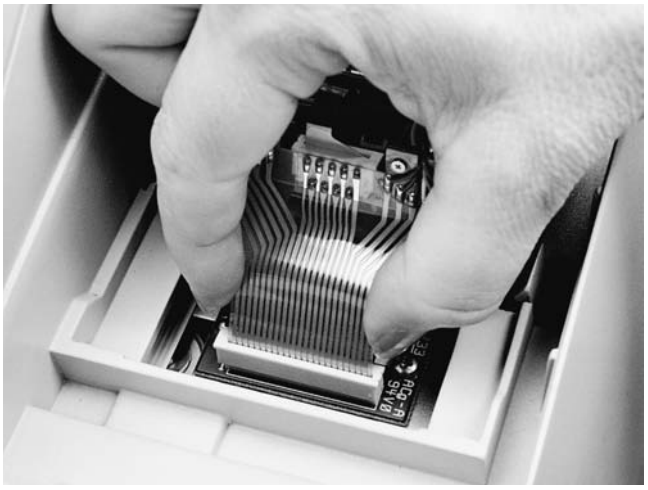


Figure 7-4

5. **To replace the printer:**
   a. Obtain the replacement printer and set it partially into position in the cavity of the instrument.
   b. Slide the interface cable into the narrow slot on the top plate of the connector. It will slide in very easily to an initial stop; at this point, firmly but carefully press the cable *straight down* until it stops again. Be sure both sides of the cable are fully inserted. Press down on both sides of the connector until it snaps shut. Gently pull up on the cable to ensure that it is secured in place. If it pulls out easily, unsnap the connector and repeat this step.

c. Place the printer fully into position by lowering the front of the module down and forward under the ledge. Then lower the back of the module and press down firmly until it snaps into place.

d. Replace the clear shield to its position in front and on top of the printer and press gently against the adhesive pads.

e. Replace the roll of paper, as instructed in Section 5, "Changing the Paper."

f. Plug in and turn *on* the CLINITEK 500 instrument. Test the new printer by printing the instrument setup parameters (from the **Ready/Run** screen, touch **Menu,** then **Print,** then **Setup report**) or by performing several Reagent Strip tests. (If you had turned the internal printer *off* prior to replacement of the module, be sure to turn it back *on* through the **Setup** Routine.)

   NOTE: If "`Printer Error`" is displayed when attempting to print, check for a tight and proper connection of the interface cable.

Calibrating the Touch Screen

If the touch screen does not respond correctly when a key is touched, the screen may need to be calibrated. This is easily done, as follows:

1. Turn the instrument power *off.* Wait several seconds, then turn the power back *on.*
2. When the title screen is displayed (which contains the software version and copyright information), touch the screen anywhere.
3. The display will prompt "`Touch the top left corner`" and an "X" will be displayed in one corner. Touch the screen, directly on top of the "X". Repeat when the prompt changes to "`Touch the bottom right corner.`" When the touch screen has been recalibrated, the display will automatically continue in the normal sequence of screens.

TROUBLESHOOTING AND SERVICE

General Information

Your CLINITEK® 500 Analyzer will give you troublefree operation if you follow the directions for using and cleaning the instrument. If an operational or instrument problem occurs, however, an error number may be displayed on the Analyzer screen, along with an explanation of the problem. This section of the manual lists the various errors and messages, along with probable causes and recommended remedies to quickly and easily correct the problem. If the problem persists after following the recommended remedy, record the error number being displayed and contact your Bayer Customer Service office for assistance.

If the Bayer Reagent Strips seem to be causing the problem, carefully read the direction insert that comes with the Reagent Strips for information that might help solve the problem.

If an error number is displayed that requires the instrument to be turned *off,* all samples that were in process when the error occurred will need to be retested. The normal end-of-run reports will be displayed when the instrument is turned back *on* for samples that had been processed prior to the error.

With some errors, the instrument will continue to run while the error is displayed. Return to the **READY/RUN** screen by touching the ⮉ key (when it is displayed) before attempting to correct the error. If another error occurs while the previous error is being displayed, the new error will be displayed in its place.

NOTE: If the instrument is turned *off* from any screen other than **Ready/Run** (and with the run completed), the moving table may not be in its lowest position. If the fixed platform is then removed, the moving table will be pulled out at the same time. You will then be unable to reinstall the fixed platform because the pins of the moving table will be in the way. To resolve this problem:

- Turn the power *on* and let the system initialize. An error will be displayed because the fixed platform is not in place, but the moving table will be rotated into the correct position.
- Turn the power *off* again.
- Install the platform.
- Turn the power *on.*

When to Call for Assistance:

- If the error message continues to be displayed after performing the steps described on the screen and in the Troubleshooting Chart;
- If additional assistance is required concerning an instrument problem;
- If the problem is beyond the scope of this manual; or
- If the problem cannot be solved and an instrument failure is apparent:

Our Customer Service Department is available to help you. Before calling, please complete the “Preservice Checklist” later in this section (you may want to make a photocopy of the checklist first). This information will help the Customer Service Representative to identify the probable cause of the problem.

Where to Call for Assistance:

If you are located in the United States, contact the Technical Care Center of Bayer HealthCare by calling toll free:

1-877-229-3711

The office is open from 8:00 AM to 8:00 PM Eastern time, Monday through Friday.

If you are located in a country other than the United States, call the Bayer office nearest you:

AUSTRALIA
Bayer Diagnostics
2 Keith Campbell Court
Scoresby VIC 3179
Telephone (toll free): 1800 034 490

BELGIUM
Bayer—Diagnostics Division
Zaventemsesteenweg, 97
B-1831 Diegem
Tel.: 02/725.18.80

CANADA
Bayer Inc.
Healthcare Division
77 Belfield Road
Toronto, Ontario M9W 1G6
Telephone: 416-248-0771
1-888-406-2222

CENTRAL EASTERN EUROPE
Bayer Diagnostics GmbH
–MOE–
Weissenseestrasse 101
D-81539 Munich, Germany
Tel.: 49-89-69927 191
Fax: 49-89-69927 248

CZECH REPUBLIC
Bayer s.r.o.
Diagnostics Division
Litvinovska 609/3
CZ-190 00 PRAHA 9-Prosek
Tel.: 02-66101-111
Fax: 02-66101 199

DENMARK
Bayer A/S
Diagnostics
Norgaardsvej 32
DK-2800 Lyngby
Telephone: 45 23 50 00

EASTERN MEDITERRANEAN, MIDDLE EAST, AFRICA
Please contact your local distributor or:
Bayer
Export Division, M.E.E.R.A.
52, quai de Dion Bouton
92807 Puteaux Cedex
France
Tel.: 33-01-49.06.56.00

FINLAND
Bayer Oy
Diagnostics
Suomalaistentie 7
02270 Espoo
Telephone: 09-887 887

GREECE
Bayer Hellas AG
BG Diagnostics
54A, Akakion St.
151 25 Amaroussion
Athens
Tel.: 1-6883700

HUNGARY
Bayer Hungaria Kft.
Palya utca 4-6
H-1012 Budapest
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Fax: 01-212 1575

INDIA
Bayer Diagnostics India Limited
589, Sayajipura
Ajwa Road
Baroda 390 019
Gujarat
Tel.: 265 462720

ITALY
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Divisione Diagnostici
Via Grosio 10/4
20151 Milano
Tel.: 02-3978.3956

KOREA
Bayer-Sankyo Co., Ltd.
c/o Hanil Pharmaceutical Ind.
656-408 Sungsu 1 KA 2-Dong
Sungdong-Ku
Seoul
Tel.: 2 4609 600

MALAYSIA
Bayer Malaysia Sdn. Bhd.
19th & 20th Floor
Wisma MPSA
Persiaran Perbandaran
40708 Shah Alam, Selangor
Darul Ehsan
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NETHERLANDS
Bayer BV
Diagnostics Division
Energieweg 1/P.O. Box 80
3641 RT/3640 AB
Mijdrecht
Telephone: 0297-280660

NEW ZEALAND
Bayer New Zealand Ltd.
Heath Care Division
3 Argus Place
Glenfield
Auckland
Telephone: (9)4444133 ext. 311

NORWAY
Bayer AS
Brennaveien 18
1483 Skytta
Telephone: 67068600

POLAND
Bayer Sp.z.o.o.
Diagnostics Division
ul. Stawki 2
00-193 Warszawa
Tel.: 22-635 6818
Fax: 22-635 5987

PORTUGAL
Bayer Portugal SA
Rua Quinta do Pinheiro, 5
Outurela
2795 Carnaxide
Tel.: (01) 416 43 11

RUSSIAN FEDERATION
A/O Bayer
Vertretung Moscowu
Bolshoi Trjechgornyi Pereulok, 1
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123 022 Moscow
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Fax: 095-234 2070

SOUTHEAST ASIA
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TAIWAN
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10F-1, NO 35
Fu-Hsing N. Road
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THAILAND
Bayer Thai Co. Ltd.
Diagnostics Business Group
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130/1 North Sathorn Road
Bangkok 10500
Telephone: 2-232 70 00

U.K.
Bayer Plc—Diagnostics Division
Bayer House
Strawberry Hill
Newbury RG14 1JA
Telephone: 01635 566211
Fax: 01635 566277

TROUBLESHOOTING CHART

SYMPTOM	POSSIBLE CAUSE	REMEDY
Changes made to **Setup** Routine are not saved.	The **Return to Ready/Run** key (⏎) was not touched after changes were made.	Always touch ⏎ after all changes have been made to the **Setup** Routine.
Display is blank.	1. No power.	1. Listen for the fan; if it is not running, turn the instrument power *off.* Check that the power cord is firmly plugged into the instrument and into a live AC electrical outlet. Then turn the power back *on.*
	2. Improperly inserted program card.	2. Turn the instrument power *off,* then remove the program card and reinsert it firmly, making sure that the label is facing forward, with the arrows pointing in and up. When properly inserted, the edge of the card will be flush with the instrument case. Turn the power back *on.*
	3. Defective program card or defective system electronics.	3. Contact your Bayer Customer Service office.
Fixed platform cannot be installed.	The moving table is not in the lowest position (see NOTE in "General Information" earlier in this section).	Turn the power *on* and let the system initialize. Ignore the error that is displayed. Turn the power *off* again, install the platform, then turn the power *on.* If still unable to install the platform, contact your Bayer Customer Service office.
Printout does not contain all reports.	"Missing" reports have been flagged for the Confirmatory Report, and "Edit flagged results" is ON.	The list of flagged reports will be displayed when the run is complete, and the reports will be printed after the End-of-Run Report screens have been exited.
Push bar does not move to the right after a strip is placed onto the platform.	1. Other strips are being moved along the platform.	1. Allow up to 7 seconds to elapse prior to movement of the push bar. The time lapse depends upon the timing cycle for movement of the strips across the platform.
	2. Strip sensor problem.	2. From the **Ready/Run** screen (and with the run completed), turn the instrument power *off,* wait several seconds, then turn it back *on.* If the problem continues, contact your Bayer Customer Service office.

SYMPTOM	POSSIBLE CAUSE	REMEDY
Push bar does not move back to the left after moving a strip.	1. The last strip has been placed in a loadlisted run, or the instrument is waiting for entry of an ID. 2. A very dark urine is being tested; the strip sensor is unable to verify the presence of the strip until it reaches the first readhead.	1. The instrument is functioning properly. Begin a new loadlisted run (after the current run is complete) or enter the ID number being requested. 2. Presence of the strip will be verified at the first readhead, requiring an additional 3 cycles (21 seconds). The push bar should then move back to the left. Continue testing in the normal manner.
Push bar moves to the right when it shouldn't (a strip has not been placed on the platform).	1. The strip sensor was accidentally triggered by a hand, sleeve, or other foreign object. 2. Strip sensor problem.	1. The push bar will move back to the left after 3 cycles (21 seconds); continue testing in the normal manner. Be sure you do not place your hand or other objects on the platform, as these can be mistaken for a Reagent Strip. 2. From the **Ready/Run** screen (with the run completed and the strip loading station clear of all strips and foreign objects), turn the instrument power *off,* wait several seconds, then turn it back *on* to recalibrate the strip sensor. If the problem continues, contact your Bayer Customer Service office.
Test results are not being printed by the internal printer.	1. Internal printer is set to OFF. 2. No paper installed in printer. 3. Paper is misfed (accompanied by an unusual noise). 4. Loose electrical connection to the printer. 5. Defective printer.	1. Set the internal printer to ON through the **Setup** Routine (see Section 3, Step A-4). 2. Install a new roll of paper as instructed in Section 5, "Changing the Paper." 3. Open the printer cover and check the paper path. Reinstall if necessary (see Section 5, "Changing the Paper"). 4. Carefully remove and reinstall the interface cable to the printer (see Section 7, "Printer Replacement," Steps 4 and 5). 5. Run the Printer test (see Section 3, Step J-2f). Contact your Bayer Customer Service office if it doesn't print correctly.
Touch screen does not respond correctly.	1. Screen needs to be recalibrated. 2. Defective screen.	1. Recalibrate as instructed in Section 7, "Calibrating the Touch Screen." 2. Contact your Bayer Customer Service office.

ERROR DISPLAY	POSSIBLE CAUSE	REMEDY
Error 01 Error 02 Error 03 Error 04 Error 05	Instrument optical error.	Turn the instrument power *off,* wait several seconds, then turn it back *on.*
Error 06-2	A Reagent Strip that had been detected at the first readhead was not detected at the second readhead.	Touch ⊽ to cancel the run and return to the **Ready/Run** screen, then turn *off* the instrument power. Remove the fixed platform to locate the strip (see Section 5, "Daily Cleaning"). Check the pins on the moving table to ensure that none are bent or broken, then perform the "Daily Cleaning" procedure in Section 5. Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results; retest those specimens.
Error 07-1	A Reagent Strip either is not fully wetted or is upside-down on the platform.	If the error is because of an upside-down strip, remove and clean the push bar, fixed platform, and holddown (see Section 5, "Daily Cleaning"). Then check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results. Retest the appropriate specimen, ensuring that the strip is dipped completely into the specimen and is placed onto the platform with the pads facing up.
Error 08-n Error 09-n	A Reagent Strip has become misaligned during processing.	Check the right side of the read station area and remove any strips that have not fallen into the waste bin. Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results. Retest those specimens, ensuring that the end of the strip is placed **against the rear wall of the platform** (with Error 08-1) and not touching the bottom of the strip loading station. If the error repeats, remove and clean the moving table, fixed platform, push bar, and holddown (see Section 5, "Daily Cleaning"). Check the moving table to ensure that no pins are bent or broken, then reinstall the parts. Ensure that the fixed platform is **fully** pushed in on both sides.

ERROR DISPLAY	POSSIBLE CAUSE	REMEDY
Error 10-n	Instrument optical error.	Turn the instrument power *off,* then remove and clean the fixed platform, taking care to carefully clean the calibration bars (see Section 5, "Daily Cleaning"). Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results; retest those specimens.
Error 21	Internal memory error.	Turn the instrument power *off,* wait several seconds, then turn it back *on.*
Error 23	1. Moving table is misaligned.	1. Turn the instrument power *off.* Remove the push bar, fixed platform, and moving table (you may have to pull firmly to remove). Turn the power back *on,* allow the system to reinitialize and the table mechanism to move to its lowest position (another error will be displayed), then turn *off* again. Reinstall the moving table (ensuring it is pushed in completely), fixed platform, and push bar, as directed in Section 5, "Daily Cleaning." Turn the power *on* again.
	2. Instrument mechanical error.	2. Contact your Bayer Customer Service office.
Error 24 Error 25	1. Fixed platform is misaligned or push bar is installed incorrectly (misaligned or upside down).	1. Turn the instrument power *off.* Inspect the instrument for any obvious signs of misalignment or incorrect installation of the push bar, fixed platform, or holddown. Remove and reinstall, if needed, as directed in Section 5, "Daily Cleaning." Be sure the feet on the push bar are on the bottom, nearest the platform. Turn the power back *on.*
	2. Instrument mechanical error.	2. Contact your Bayer Customer Service office.
Error 26	Fixed platform is missing or not installed properly.	Install the table and platform, if missing (see Section 5, "Daily Cleaning"). If already installed, carefully push in on the sides of the platform to make sure it is fully engaged. If the error continues, remove and reinstall the platform, as instructed in Section 5.

ERROR DISPLAY	POSSIBLE CAUSE	REMEDY
Error 27	Holddown is improperly installed or missing, or is dirty.	Remove the fixed platform as instructed in Section 5, "Daily Cleaning." Install the holddown if missing, or clean it if it appears dirty. Reinstall the holddown, ensuring it is properly installed, then replace the platform onto the instrument. (If the holddown appears damaged or discolored, replace with a new holddown.) Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results; retest those specimens.
Error 28	A Reagent Strip that was detected as being placed on the platform was not detected at the first readhead.	**If a strip was never placed or was removed after being placed:** Check your printout of results, or the Results Error Report displayed at the end of the run, to determine if a result set is missing and, if so, retest the specimen. Be sure you do not place your hand or other objects on the strip loading station, as these can be mistaken for a Reagent Strip. If the error occurs repeatedly, turn the instrument power *off,* wait several seconds, then turn it back *on* to recalibrate the strip sensor. **If a strip was present:** Remove and clean the moving table, fixed platform, and holddown (see Section 5, "Daily Cleaning").
Error 29	1. Shipping foam is still in place (first time the instrument is powered *on,* accompanied by a loud noise). 2. Calibration bar error.	1. Turn the instrument power *off* and remove the foam (see Section 2, "Unpacking," Step 4). 2. Turn the instrument power *off,* then remove the fixed platform (see Section 5, "Daily Cleaning") and inspect the calibration bars for damage or misalignment. Clean the platform and calibration bars and reinstall the platform. Turn the power back *on.*
Error 30 Error 31 Error 34	Instrument mechanical error.	Contact your Bayer Customer Service office.
Error 36	Both areas of instrument memory where factory calibration parameters are stored have been corrupted.	Turn the instrument power *off,* wait several seconds, then turn it back *on.* If the error repeats, contact your Bayer Customer Service office.

ERROR DISPLAY	POSSIBLE CAUSE	REMEDY
Error 50	Printer Error	Check that your external printer is turned *on* and is on-line. Verify that both ends of the interface cable are securely connected and check that your printer has paper.
Error 51 Error 52	Control results memory (51) or sample results memory (52) is almost full.	Nearly 200 control result sets or nearly 500 patient result sets have been stored in memory without being transferred to a computer. Check that your computer is turned *on,* that the interface cable is securely connected at both ends, and that the setup parameters for the computer interface are correct. Transfer at least some of the records. If unable to transfer records, contact your Bayer Customer Service office.
Error 53 Error 54	Control results memory (53) or sample results memory (54) is completely full.	Two hundred control result sets or 500 patient result sets have been stored in memory without being sent to a computer. No additional testing can occur until at least some of the records are transmitted. Check that your computer is turned *on,* that the interface cable is securely connected at both ends, and that the setup parameters for the computer interface are correct.
Error 55	Both areas of instrument memory where the Setup parameters are stored have been corrupted. The manufacturer's defaults have been restored.	Print a Setup report (see Section 3, "When Setup is Complete") to view the default parameters. If you previously printed and saved a copy of the Setup report of your customized selections, compare the two reports. Reselect the options that need to be changed.
Error 56	System error.	Turn the instrument power *off,* wait several seconds, then turn it back *on.* If the error repeats, contact your Bayer Customer Service office.

CLINITEK® 500
Preservice Checklist

(Suggestion: Make photocopies of this clean page.)

For reference, record the following information:

Model / Serial Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ Installation Date: _____

	YES	NO
1. Does the fan come on when the instrument is turned *on?*	☐	☐
• If NO, is the instrument firmly plugged into a live AC electrical outlet and into the instrument?	☐	☐
2. Is the appropriate sequence of screens displayed when the instrument is first turned *on?* (See Section 2 for a description of the screens.)	☐	☐
• If NO, is the Program Card firmly in place and properly oriented? (See Section 2, "Instrument Setup," Step 5.)	☐	☐
3. Is the touch screen operating properly?	☐	☐
If NO:		
• Have you performed the Touch Screen Test? (See Section 3, Step J-3c.)	☐	☐
• Have you recalibrated the touch screen? (See Section 7.)	☐	☐
4. Does the instrument proceed properly while analyzing Reagent Strips?	☐	☐
5. Is the printer functioning properly (i.e., are the appropriate messages and patient results being printed)?	☐	☐
If NO:		
• Is the internal or an external printer turned ON? (See Section 3, Step A-4.)	☐	☐
• Is there paper in the printer?	☐	☐
• Have you performed the printer test? (See Section 3, Step J-2f.)	☐	☐
6. Are reasonable results being displayed/printed for the controls and patient samples?	☐	☐
If NO:		
• Does the name of the Bayer Reagent Strip displayed on the **Ready/Run** screen agree with the strip being used?	☐	☐
• Are the Bayer Reagent Strips within their expiration dating?	☐	☐
• Is the bottle of Control Strips within its expiration dating and is the Control Solution within its use life (8 hours)?	☐	☐
• Is the instrument in the proper operating environment and location? (See Section 2.)	☐	☐
• Is the fixed platform clean? (See Section 5.)	☐	☐
7. What is the software revision level being used? (Turn the Analyzer *off,* wait about 15 seconds, then turn it back *on;* the software version is displayed after the initialization screen.) _____		
8. Are any error messages or warnings being displayed?	☐	☐
• If so, what are they? (List the error description and any numbers that are displayed.) _____ _____		
9. Have you performed the appropriate steps suggested on the display for the error being displayed?	☐	☐
If an external device is being used:		
10. Is the printer and/or host computer/LIS connected and turned *on?*	☐	☐
11. Have the correct parameters for transmission been selected (through the **Setup** menus)?	☐	☐
12. Is the external printer properly printing the test results?	☐	☐
13. Is the computer receiving the proper data (e.g., do the results correspond with the screen display)?	☐	☐

SUPPLIES & REPLACEMENT PARTS

Supplies/Optional Equipment

Catalog Number	Description
*	Bayer Reagent Strips for Urinalysis
1364	CHEK-STIX® Combo Pak Control Strips for Urinalysis (U.S.A and Canada)
1364E	CHEK-STIX® Combo Pak Control Strips for Urinalysis (all other countries)
1360	CHEK-STIX® Positive Control Strips for Urinalysis
6469	CLINITEK® 500 Handheld Bar Code Reader
5773	Thermal Printer Paper (5 rolls)
6472	CLINITEK® 500 Waste Bin Liners (package of 5)
5257	STAR Form Printer
RC200P	STAR Form Printer Ribbon Cassette (1)
5256	CLINITEK® Form Printer Ribbon Cartridge
5163A	CLINITEK® 3-Copy Forms (10 x 100)

Where to Order:

In the United States, the above supplies and optional equipment are available from your authorized CLINITEK® 500 distributor.

Outside of the United States, contact the nearest Bayer office (see Section 8, “Where to Call for Assistance”).

Replacement Parts

Part Number	Description
**	AC power cord
**	CLINITEK® 500 Operating Manual
99964708	CLINITEK® 500 Service Manual
50084369	Color/Clarity Card (for use with Handheld Bar Code Reader)
95002457	Fixed platform and holddown
50210070	Holddown plate
71520103	Loopback connector
50577530	Moving table
40451012	Printer
50062319	Printer cover
50540224	Push bar

Where to Order:

In the United States, the above Replacement Parts are available directly from:

Customer Service Order Entry Dept.
Bayer HealthCare LLC
P.O. Box 2004
Mishawaka, IN 46546-9979
1-800-348-8100

Outside of the United States, contact the nearest Bayer office (see Section 8, “Where to Call for Assistance”).

*Contact your Bayer office or representative for the configurations and catalog numbers available in your country.

**Contact your Bayer office or representative for the part number appropriate for your location.

COMPUTER AND PRINTER INTERFACE

General Information

The CLINITEK® 500 Urine Chemistry Analyzer can be interfaced to a host computer or LIS (Laboratory Information System) via the serial port on the instrument (labeled "10101"). It can also be interfaced to an 80-column or form printer through the parallel (Centronics) port (labeled "◎"). This appendix contains the specifications for the interface cables needed to accomplish these interfaces. Additional information needed to write a program to interface the CLINITEK 500 Analyzer with a computer can be obtained from your nearest Bayer Customer Service Department or office.

Cable and Pin Specifications — Serial Port

The cable normally used to interface with the CLINITEK 500 instrument is a Null modem cable. This cable crosses pins 2 and 3, 4 and 5, and 6 and 20; pins 1 and 7 are straight through. Refer to **Table CPI-1** for definitions of the pin assignments and hardware handshaking.

Cable and Pin Specifications — Parallel Port

The printer (parallel data) port is of the "Centronics" style of interface with a DB-25 connector and is provided for use with either of two types of printers:

1. Any standard 80-column printer having a Centronics style of interface — the External Printer option must be set to "ON, 80 Column" in the **Setup** Routine (Section 3, Step A-4a-iii). The interface cable that is used to connect the 80-column printer to the CLINITEK 500 instrument must contain a DB-25 male connector (standard IBM configuration). Refer to **Table CPI-2** for definitions of the pin assignments.
2. Form Printers — three special formats of data are generated for use with various form printers when the External Printer option is set to "ON, Form Printer 1," "ON, Form Printer 2," or "ON, Form Printer 3" in the **Setup** Routine (Section 3, Step A-4a-iii).
   - **Form Printer 1** creates a format that is appropriate for use with the Printer Products Form Printer. It adds 9 spaces to the beginning of each line so the results align in the proper location on the CLINITEK® Report Form. The display includes a "Reprint" key that can be used if a record needs to be reprinted.
   - **Form Printer 2** is appropriate for use with the CLINITEK® Form Printer. The results are transmitted without any additional spaces in front of each line. Records are reprinted using the "Reprint" key on the Form Printer.
   - **Form Printer 3** can be used with the Star Form Printer (Bayer Product No. 5257) and other simple form printers. This format includes a command to the printer that prevents it from printing a record until a form is in place. It also includes a command to eject the form out of the front of the printer. The CLINITEK 500 display includes a "Reprint" key that can be used if a record needs to be reprinted. Extra spaces are not transmitted with this format.

   If you are unsure of which format to use, print a record using each of the Form Printer options to determine which one provides the best placement of the printed results on the form and works appropriately with your form printer.

Pin Assignments for Interface Cable — Serial Port

Pin Number	Signal Name	Function	Type	Signal Source
1	CHAS GND	Protective Ground	Ground	N/A
2	TXD	Transmit Data	Data	CLINITEK 500
3	RXD	Receive Data	Data	Computer
4	RTS	Request To Send	Control	CLINITEK 500
5	CTS	Clear To Send	Control	Computer
6	DSR	Data Set Ready	Control	Computer
7	SIG GND	Signal Ground	Ground	N/A
20	DTR	Data Terminal Ready	Control	CLINITEK 500
	(All other pins are unused.)			

Hardware Handshaking:

RXD	Receive Data	This input receives control characters for software handshaking and data for IDs.
TXD	Transmit Data	This output sends test data, control characters, and instrument information.
DTR	Data Terminal Ready	This signal is on whenever the instrument I/O is configured for a computer and the instrument is *on.*
DSR	Data Set Ready	The computer must raise this line whenever it is ready to receive data. If not supplied by the computer, pin 6 must be jumpered to pin 20.
RTS	Request To Send	This output line, when high, indicates to the computer that it may send data.
CTS	Clear To Send	This input is checked before sending each character and, if high, the next character is sent. If not supplied by the computer, pin 5 must be jumpered to pin 4.

The following signal lines are NOT implemented:

DCD	Data Carrier Detect	Pin 8
RNG	Ring Indicator	Pin 22

Table CPI-1

Pin Assignments for Interface Cable — DB-25 Male Connector

Pin Number	Signal Name	Function	Note	Signal Source
1	STROBE-L	Data Strobe	1	CLINITEK 500
2	Data 1	Parallel Data Line		CLINITEK 500
3	Data 2	Parallel Data Line		CLINITEK 500
4	Data 3	Parallel Data Line		CLINITEK 500
5	Data 4	Parallel Data Line		CLINITEK 500
6	Data 5	Parallel Data Line		CLINITEK 500
7	Data 6	Parallel Data Line		CLINITEK 500
8	Data 7	Parallel Data Line		CLINITEK 500
9	Data 8	Parallel Data Line		CLINITEK 500
11	BUSY	Busy Line		Printer
12	PRINTER OUT	Printer Out Line		Printer
18	SIG GND	Signal Ground	2	N/A

NOTES:
1. STROBE-L (Data Strobe): "-L" indicates active low signal.
2. SIG GND (Signal Ground): Pins 19 through 25 are also connected to the signal ground.

Table CPI-2

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CLINITEK® 500
Urine Chemistry Analyzer

Please record the following information.
Keep this sheet in the operating manual for future reference.

Date of Installation

Model/Serial Number

MANUFACTURER'S WARRANTY

(U.S. Customers Only)

Bayer HealthCare LLC ("Bayer") warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for a period of one year from the later of the date of original purchase or installation (except as noted below). During the stated one-year period, Bayer shall replace with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective.

This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost, and Bayer shall not be required to make any repairs or replace any parts which are necessitated by abuse, accidents, alteration, misuse, neglect, maintenance by other than Bayer, or failure to operate the instrument in accordance with instructions. Further, Bayer assumes no liability for malfunction or damage to Bayer instruments caused by the use of reagents other than reagents manufactured or recommended by Bayer.
3. Bayer reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

Disclaimer of Warranties

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE WHICH ARE EXPRESSLY EXCLUDED, AND IS THE ONLY WARRANTY GIVEN BY BAYER.

Limitations of Liability

IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service, purchaser must contact the Technical Care Center of Bayer HealthCare by calling toll free 1-877-229-3711, for assistance and/or instructions for obtaining repair of this instrument.